Filed on behalf of: Medtronic, Inc.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Medtronic, Inc.
Petitioner
v.
NuVasive, Inc.
Patent Owner

Case _____
U.S. Patent No. 8,016,767

DECLARATION OF DAVID HACKER

I, David Hacker of Duval County, Jacksonville, Florida, declare that:

1. I am the Principal Engineer, Research and Development, for Medtronic, Inc., in the Surgical Technology Division. I have worked as an engineer on Nerve Integrity Monitor (NIM) systems for surgical applications since 1989. Specifically, from 1989 to 1999, I worked on NIM systems for Xomed, Inc. In 1999, Xomed, Inc. was acquired by Medtronic, Inc. I have continued to work on NIM systems for Medtronic, Inc. since that acquisition.

2. My work on NIM systems has involved reviewing user manuals that are provided with the NIM products sold by Medtronic, Inc. (and previously Xomed, Inc.). These user manuals are shipped with the corresponding product to customers who buy the product.

3. Being submitted with this Declaration as Attachment A is one such manual, which is entitled NIM-Response – Nerve Integrity Monitor/Intraoperative EMG Monitor – User's Guide ("User Guide"). The User Guide was a user manual for the NIM-Response 82-50001 Mainframe product ("NIM-Response product") and was shipped with the product to customers.

4. The User Guide has a copyright date of 2000 on the page following the title page. I note that the User Guide has a date of "03/00" on the last page. This indicates that this version (Revision B) of the User Guide was finalized in March 2000. The User Guide also has a handwritten "4/4/2000" notation at the top of the title page. This indicates that the User Guide was approved for release with the corresponding product on April 4, 2000.

5. In addition, I have attached a copy of a Work Order for the NIM-Response product as Attachment B to this Declaration. Work orders document the date that a product was built and includes, among other things, the first and last page of the

user manual that is included with the product when the product is shipped. The attached Work Order is for a NIM-Response product built in May 2000 and has a Lot No. 19727500. The first and last page of the manual attached to the Work Order confirms that the manual shipped with the product was the same User Guide as Attachment A. The date stamped at the bottom of the Work Order indicates that the NIM-Response product with this particular User Guide was built and ready for shipment on May 26, 2000.

6. I attach as Attachment C to this Declaration, a Sales Record for the NIM-Response product for May 26, 2000. I note that the Lot No. is the same as that of the Work Order above, Lot No.19727500. This Sales Record confirms that on May 26, 2000, the product and the accompanying User Guide was shipped to customers.

7. I have also attached a copy of the Work Order History from 2000-2001 for the NIM-Response product as Attachment D to this Declaration. The Work Order History shows that the NIM-Response product was continuously built and shipped (with accompanying manual) throughout 2000-2001. At least as early as May 26, 2000, the manual shipped with the product was the User Guide.

8. Thus, based on my review of the User Guide, Work Order, Sales Record, and Work Order History, the User Guide was provided to customers, outside of Medtronic, Inc., who bought the corresponding product, at least as early as May 26, 2000. Those customers included hospitals and clinics in the United States and other countries. Medtronic, Inc. did not restrict the customers' use or dissemination of the User Guide.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code.

Date: 10-10-2013

David Hacker

ATTACHMENT A

Approved WWG 4/4/

NIM-Response™

NERVE INTEGRITY MONITOR

Intraoperative EMG Monitor

USER'S GUIDE

"OBSOLETE"

Medtronic
XOMED

NIM-Response Helpline
1-800-874-5797
For Questions and Service

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MEDTRONIC XOMED SURGICAL PRODUCTS, INC.
6743 Southpoint Drive North
Jacksonville, FL 32216

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CE 0123

This device complies with Medical Device Directive 93/42/EEC

Authorized Representative (for EC regulatory matters)
Medtronic Xomed U.K. Limited
Unit 5, West Point Row
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Bristol B532 4QG
England

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SYMBOLS

	ATTENTION, SEE INSTRUCTIONS FOR USE
REF	CATALOG NUMBER
SN	SERIAL NUMBER
	DATE OF MANUFACTURE
	USE BY DATE
	DO NOT REUSE
	STERILIZED BY ETHYLENE OXIDE. DO NOT USE IF PACKAGE IS OPENED OR DAMAGED.
	LOT NUMBER
	CE MARK
	OFF
	ON
	OFF
	ON
	VOLUME
	RELATIVE SCALE INDICATOR
	EXIT POP-UP WINDOW
	HELP
	TYPE BF APPLIED PART
	PATIENT CABLE
	FUSE
	INPUT
	OUTPUT
	FOOTSWITCH CONNECTION

NOTICE

It is important that you read this entire manual before you use the NIM-Response Monitor. It is unsafe to use this device before you have read and are thoroughly familiar with this document.

⚠ WARNINGS AND PRECAUTIONS

It is important that the NIM-Response operator be familiar with this manual: its precautions, procedures and safety issues. Three labels are used in this manual to identify important concerns, conditions, or procedures:

"⚠ WARNING"

Identifies conditions or practices that present a risk of injury to the patient and/or user.

"⚠ CAUTION / PRECAUTIONS"

Identifies conditions or practices that could result in damage to the equipment.

"⚠ IMPORTANT"

Identifies conditions or practices which require attention for most desirable monitoring results.

⚠ WARNINGS

- THE USE OF PARALYZING ANESTHETIC AGENTS WILL SIGNIFICANTLY REDUCE, IF NOT COMPLETELY ELIMINATE, EMG RESPONSES TO DIRECT OR PASSIVE NEURAL STIMULATION.
- AUDITORY AND VISUAL MONITORING ARE DISABLED WHILE MUTING IS IN EFFECT.
- THIS SYSTEM IS NOT EXPLOSION-RESISTANT. THEREFORE, IT IS NOT TO BE USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.
- TO MINIMIZE THE RISK OF BURNS TO THE PATIENT INCLUDING CASES WHERE MORE THAN ONE SURGEON IS OPERATING (I.E. FAT HARVESTING), NEVER LEAVE THE STIMULATOR IN THE FIELD, ON A MAGNETIC TRAY, OR IN THE ELECTROSURGICAL HOLDER DURING ELECTROSURGICAL USE.
- TO AVOID EYE INJURY DURING ELECTRODE PLACEMENT, THE ELECTRODE NEEDLES SHOULD BE DIRECTED AWAY FROM THE ORBIT WHEN INSERTED FOR ORBICULARIS OCULI MONITORING.
- DO NOT TURN POWER TO THE NIM-RESPONSE ON WHEN THE STIMULATOR IS IN THE FIELD. UPON APPLICATION OF POWER, A PULSE OF 5 MA MAY BE DELIVERED FOR LESS THAN 0.01 S. THIS MAY BE EXCESSIVE FOR SOME MONITORING APPLICATIONS.
- ANY CONNECTIONS MADE TO LPT1 OTHER THAN THE THOSE RECOMMENDED IN THIS MANUAL, MAY NOT BE ISOLATED AND RESULT IN INJURY TO THE PATIENT OR OPERATOR.
- THE NIM-RESPONSE DOES NOT PREVENT THE SURGICAL SEVERANCE OF NERVES. MONITORING IS ONLY A TECHNICAL AID TO IDENTIFICATION AND LOCATION OF NERVES; IT DOES NOT REPLACE THE SURGICAL SKILLS, EXPERIENCE, AND ANATOMICAL KNOWLEDGE NECESSARY TO VISUALLY LOCATE NERVES AND SURGICALLY AVOID THEIR SEVERANCE.

⚠ PRECAUTIONS

- DO NOT CONNECT ANY DEVICE OTHER THAN NIM-RESPONSE MUTING PROBES INTO ANY OF THE FOUR MUTING PROBE INPUTS ON THE REAR PANEL OF THE NIM-RESPONSE. SYSTEM DAMAGE MAY RESULT.
- DO NOT MODIFY THE NIM-RESPONSE OR EXTEND THE CABLES OF THE MUTING PROBE OR PATIENT INTERFACE. SUCH MODIFICATIONS OR EXTENSIONS COULD SIGNIFICANTLY AFFECT SYSTEM PERFORMANCE.
- TURN OFF POWER TO THE NIM-RESPONSE OR NIM-RESPONSE PRINTER BEFORE CLEANING. TO PREVENT CLEANING SOLUTIONS FROM SEEPING INTO THE ELECTRONIC PORTIONS OF THE INSTRUMENT, SPRAY CLEANER LIGHTLY ON A COTTON CLOTH, THEN WIPE THE INSTRUMENT WITH THE CLOTH. BE ESPECIALLY CAREFUL AROUND THE CONTROLS, CONNECTORS AND PANEL EDGES. DO NOT USE ABRASIVE CLEANERS.
- ATTEMPTED REPAIR OR EVIDENCE OF ATTEMPTED REPAIR BY ANYONE OTHER THAN QUALIFIED MEDTRONIC XOMED SERVICE PERSONNEL WILL VOID THE EQUIPMENT WARRANTY.

WARNINGS AND PRECAUTIONS (CONTINUED)

⚠ IMPORTANT

- It is important to distinguish between the pulsed sound Event Tones which indicate EMG activity that is over Threshold and the Warble sound Current Delivered Tone which indicates the set current is being delivered.
- Whenever the alarm for prolonged muting occurs, the cause must be identified and eliminated immediately. If the cause is not eliminated, it may be impossible to perform valid monitoring for the remainder of the procedure.
- Always attach the MUTING PROBE around the electrocautery cord. A false "Lead Off Attention!" alert may result from non-muted, overloaded EMG signals entering the NIM-Response.
- If no "Current Delivered Tone" sounds and the measured Stimulus Current flow is less than 80% of the set amount, either no current or not enough current is being delivered to the nerve. Factors which may contribute to this include:
  - High impedance, improper flush contact between the probe and the nerve;
  - Stimulator return electrode not connected or other incomplete electrical connection between the NIM-Response and the stimulator probe; and
  - Stimulus Set to 0.00 mA.
  - Patient Cable Fuse Blown.
- The proper setup and use of the muting detector is needed for optimum monitoring. Should you experience any difficulty with the sensitivity of the muting detection, resulting in either a constant muting situation or not enough muting when the electrosurgical unit is activated, adjust the MUTING PROBE INPUT to either less muting (lower muting probe gain represented by lower jack number) or more muting (higher muting probe gain represented by higher jack number) as required by the situation.
- Stimulus artifact may be spuriously detected as EMG events if the recording electrodes and the stimulator (+) or (-) cabling become tangled. Be careful to route the recording electrodes away from stimulator cables.
- Other monitoring equipment, such as that used by the anesthesiologist, may pick up the small currents used during muting or electrodes check for ongoing electrode impedance checks. In most cases, their presence can be accommodated by the anesthesiologist or other monitor operator.
- Proper placement and setup of the ECU away from the monitor will reduce, or minimize muting, off sets and Interference.
- Do not let the conductive parts of applied needle electrodes contact each other. Proper detection of EMG activity may not occur.
- Proper NIM-Response operation cannot be guaranteed if you do not use MEDTRONIC XOMED stimulus probes, stimulus-dissection instruments or electrodes.
- After needle insertion and before the patient is draped, after the incision is closed and before the surgical drapes and electrodes are removed, check the electrode integrity by pressing ELECTRODES CHECK. This confirms that recording electrode continuity was maintained throughout the entire procedure.

CUSTOMER SERVICE

U.S. CUSTOMER SERVICE

General customer service and technical support are available toll-free:
800-874-5797 or 904-296-9600
Monday-Friday
8:00 AM - 6:00 PM E.S.T.
www.xomed.com

MICROELECTRONICS REPAIR

Technical Support:
800-872-9877
904-296-6448 (FAX)
Monday - Friday
8:00 AM - 5:00 PM E.S.T.
www.xomed.com

Return Address:
Medtronic Xomed Surgical Products, Inc.
6743 Southpoint Drive N.
Jacksonville, FL 32216
Attn.: Repair Department

INTERNATIONAL SERVICE

International customers should contact their local Medtronic Xomed office:

AUSTRALIA:	800-062-289
CANADA:	800-710-5201
FRANCE:	0470-670451
U.K.:	01454-619555
GERMANY:	08105-3755-0

or their local distributor.

THE NIM-RESPONSE HELPLINE

Should you need immediate help with a technical question or guidance through the appropriate protocol, just call the NIM-Response Help Line at **1-800-874-5797.**

NOTE: WHEN CONTACTING OUR CUSTOMER SERVICE AND TECHNICAL SUPPORT, PLEASE HAVE THE APPROPRIATE PRODUCT NUMBER, PRODUCT SERIAL NUMBER, DATE OF PURCHASE, AND NATURE OF INQUIRY AVAILABLE.

PRODUCT NUMBER _____

SERIAL NUMBER _____

DATE OF PURCHASE _____

WARRANTY

This product is sold by MEDTRONIC XOMED under the warranty herein set forth. The warranty is extended only to the buyer purchasing the device directly from MEDTRONIC XOMED.

MEDTRONIC XOMED warrants this product to be free from defects in workmanship and material under normal use and service and shall conform to its original specifications for a period of one (1) year from the date of delivery. The liability under this warranty is limited, as is sole discretion, to replacing, repairing, or issuing credit (adjusted to reflect the age of the product) for a system or a portion thereof provided that (a) MEDTRONIC XOMED is notified in writing within thirty (30) days following discovery of a defect by the buyer, (b) the defective device is returned to MEDTRONIC XOMED, and MEDTRONIC XOMED's examination of the device shall disclose to its satisfaction that (i) the device has not been repaired or altered by anyone other than MEDTRONIC XOMED, (ii) any defect has not been caused by misuse, neglect or accident, (iii) the device has not been operated under conditions other than normal use, and (iv) prescribed periodic maintenance and services have been performed with respect thereto.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall MEDTRONIC XOMED be liable for any incidental defect, failure, or malfunction of the product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.

CUSTOMER RESPONSIBILITY

This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Parts which may be broken or missing or are plainly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from MEDTRONIC XOMED. The responsibility of MEDTRONIC XOMED for a defective product is limited by the warranty set forth in this manual. Should repair or replacement of this product become necessary after the warranty period, the customer should seek advice from MEDTRONIC XOMED prior to such repair or replacement. If this product is in need of repair, it should not be used until all repairs have been made and the unit is functioning properly and ready for use. The owner of this product has sole responsibility for any malfunction resulting from improper use or maintenance, or by repair by anyone other than MEDTRONIC XOMED and from any malfunction caused by parts that are damaged or modified by anyone other than MEDTRONIC XOMED.

⚠ CAUTION

Federal law in the U.S.A. and Canada restricts the sale, distribution or use of this device to, by or on the order of a licensed medical practitioner.

1 • GETTING STARTED

DEVICE DESCRIPTION

INTENDED USE

The NIM-Response is intended for use in surgical operating theaters for patient-connected intraoperative nerve monitoring.

INDICATIONS

The NIM-Response is intended for intraoperative use during surgeries in which a motor nerve is at risk due to unintentional manipulation. The NIM-Response records electromyographic (EMG) activity from muscles innervated by the affected nerve. The monitor will assist early nerve identification by providing the surgeon with a tool to help locate and identify the particular nerve at risk within the surgical field. It will continuously monitor EMG activity from the muscles innervated by the nerve at risk to minimize trauma and enhance neural preservation by alerting the surgeon when a particular nerve has been activated.

CONTRAINDICATIONS

The NIM-Response is not for use when paralyzing anesthetic agents are being used, since they will significantly reduce, if not completely eliminate, EMG responses to direct neural stimulation.

COMPONENTS

When you unpack the NIM-Response, save the cartons and packing material in which your monitor arrived. If the instrument is to be shipped from one location to another, the custom designed shipping package will provide the best protection.

When the box is unpacked, check off the contents of the box against the items listed on the packing slip. If the contents are incomplete, or if there is damage, notify MEDTRONIC XOMED. If the shipping container is damaged, or the cushioning material shows signs of stress, notify the carrier as well. Keep the shipping materials for carrier inspection.

Ensure that the following components are present:

- NIM-Response Main Frame, 115V
  (includes U.S. Power Cord and User's Guide) ..... (82-50001)
- NIM-Response Patient Interface ..... (82-50200)
- NIM Muting Probe ..... (82-20300)
- Prass Flush-tip Monopolar Stimulator Probes (1 box of 5) (82-25101)
- NIM-Response Patient Simulator ..... (82-50600)
- 1 Box (5 sets) Paired Subdermal Electrodes ..... (82-27410)
- Printer and Accessories (optional) ..... (82-50110)

OPERATING ROOM SETUP

LOCATION

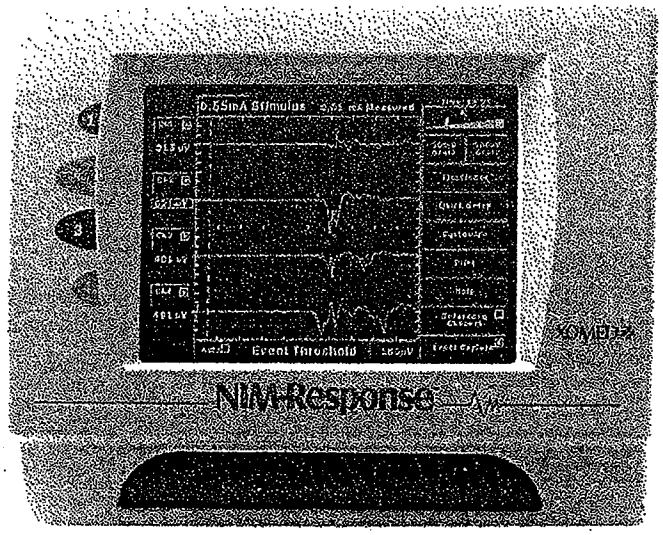
Set the NIM-Response on a table or cart located about 10 feet from the surgical field but as far as possible from the electrosurgical unit. Also consider traffic patterns and sterile areas. The surgeon may have further preferences as to location and visibility.

Clip the PATIENT INTERFACE box to the surgical bed near the head of the patient and within reach of the sterile electrode leads and sterile stimulator cable (s).

Keep the PATIENT INTERFACE cable and electrodes away from other operating room cords. When wires must cross, they should cross at right angles. Never run operating room cords parallel to any of the NIM-Response wires. Lay the PATIENT INTERFACE cable out of busy traffic patterns and secure it to the floor as needed.

Attach the MUTING PROBE to the electrosurgical unit and plug it into one of the MUTING PROBE INPUT jacks on the rear panel of the NIM-Response. Each MUTING PROBE has a cable, which may be taped to the floor.

FRONT PANEL



Front Panel of the NIM-Response Monitor

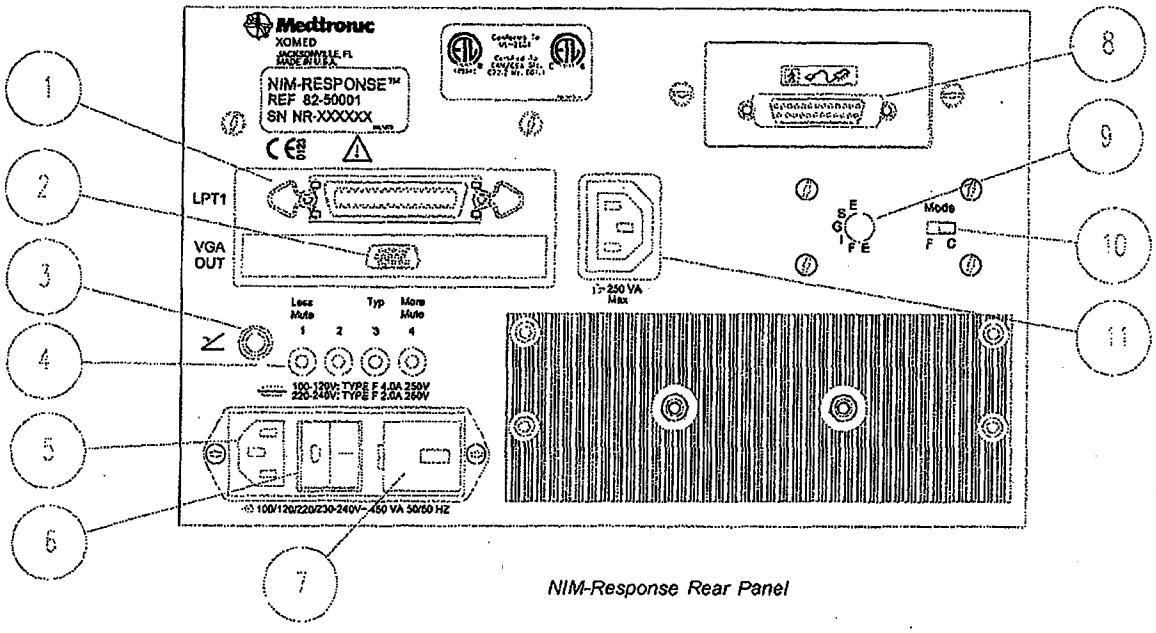
DISPLAY

The touch screen displays both EMG waveforms and controls many functions of the monitor. The complete description of these controls are in the "Software Setup" section.

SPEAKER

The SPEAKER provides audio alarms and acoustic EMG monitoring.

REAR PANEL



NIM-Response Rear Panel

1. **LPT1 OUTPUT**

   The LPT1 OUTPUT is a centronix type connector for a PRINTER, LS120, or Zip Drive.

2. **VGA OUTPUT**

   A VGA OUTPUT is available through the standard VGA 15 pin connector on the back panel. The NIM-Response can be connected directly to a VGA monitor. The VGA output can also be converted to S-VIDEO format for use with S-VIDEO VCR, the LandmarX Image Guided Surgery System, or other S-VIDEO devices.

3. **FOOTSWITCH CONNECTOR (OPTIONAL)**

   The two pedal footswitch adjusts the Stimulus up and down.

4. **MUTING PROBE INPUTS**

   There are four MUTING PROBE INPUTS on the NIM-Response Monitor. One MUTING PROBE is shipped with the system (82-50000). Plug the MUTING PROBE into MUTING PROBE INPUT #3.

5. **POWER CORD**

   The POWER CORD plugs into the back of the NIM-Response Monitor. Plug the POWER CORD into the A/C power outlet.

6. **POWER SWITCH**

   The POWER SWITCH turns the power ON or OFF.

7. **FUSE ACCESS**

   Replace with Type F 250V fuses only. For 100-120V wall power, use 4.0 A fuses. For 220-240V wall power, use 2.0 A fuses.

8. PATIENT INTERFACE CONNECTOR

The PATIENT INTERFACE CONNECTOR is a 25-pin D-sub connector which accepts the cable from the PATIENT INTERFACE BOX. Plug the PATIENT INTERFACE CABLE securely into the back of the NIM-Response at the PATIENT INTERFACE CONNECTOR and tighten the thumb screws.

9. LANGUAGE SWITCH

The LANGUAGE SWITCH is set to English by default. It may be switched to French, Italian, German, or Spanish as needed.

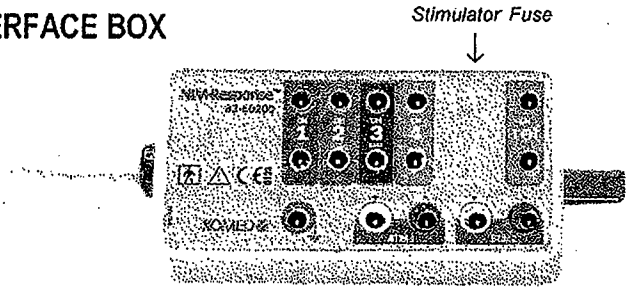
10. FACTORY / CUSTOM MODE SWITCH

The Factory/Custom mode switch allows the unit to be returned to original factory settings. To reset the software to Factory mode, move the switch to "F" and then power the unit ON. The normal mode is Custom ("C") which allows the user to save Custom configurations.

11. ACCESSORY POWER OUTLET

The Accessory Power Outlet powers perpipheral devices used with the NIM-Response System.

THE PATIENT INTERFACE BOX



Patient Interface Box and Cable

The PATIENT INTERFACE BOX and CABLE link the patient to the NIM-Response.

ELECTRODE INPUTS

Two electrodes per monitoring channel and one ground electrode are required. The positive (+) and negative (-) electrodes for each channel plug into color coded input jacks on the PATIENT INTERFACE BOX. Channel 1 is blue; channel 2, red; channel 3, violet; channel 4, orange. Plug the patient Ground into the green input jack, and the anode for the probe into the red input jack of the stimulator.

STIMULATOR OUTPUT

The NIM-Response System supports the use of two stimulation probes. Each stimulator requires two leads, one from the probe and one from the patient, to provide a complete circuit. The lead from the stimulator is the cathode and is plugged into the black, negative (-) jack. The lead from the patient is the anode and is plugged into the red, positive (+) jack. Plug the connections for the stimulator probe into the STIMULATOR OUTPUT jacks on the PATIENT INTERFACE BOX.

⚠ WARNING

DO NOT TURN POWER TO THE NIM-RESPONSE SYSTEM ON WHEN THE STIMULATOR IS IN THE FIELD. UPON APPLICATION OF POWER, A PULSE OF 5 MA MAY BE DELIVERED FOR LESS THAN 0.01 S. THIS MAY BE EXCESSIVE FOR SOME MONITORING APPLICATIONS.

STIMULATOR FUSE

Replace with Type F 32 mA 250V fuse only.

THE MUTING PROBE

A MUTING PROBE is connected around the output cable of equipment, such as bipolar electrocautery, ultrasonic debulking devices, or other external devices which generate interfering signals. Always attach the MUTING PROBE close to the output jacks of the electrosurgical or other unit rather than near the handpiece the surgeon uses. More than one output cable may be accommodated in the MUTING PROBE at one time.

To install the MUTING PROBE:

1. Open the MUTING PROBE jaws and insert the cable from the external device(s).
2. Slide the cable so the probe is near the main unit of the external device(s), not near the handpiece(s).
3. Slip the upper side of the anti-slide ring around the end of the MUTING PROBE to form a "U" around the cable. Pull it snugly against the probe's lower jaws.

MUTING PROBE INPUTS

There are four input jacks for MUTING PROBE input. These four input jacks are individually preset to represent a graduated muting gain. Input jack #1 is the least sensitive for muting detection, while input jack #4 is the most sensitive.

MUTING PROBE jack #3 provides the "typical" gain value for the muting detection feature.

Should there be a need for more or less gain, depending upon the conditions of the operating room setting or amount of detection desired from a given electrosurgical unit, simply move the muting probe into a more appropriate jack.

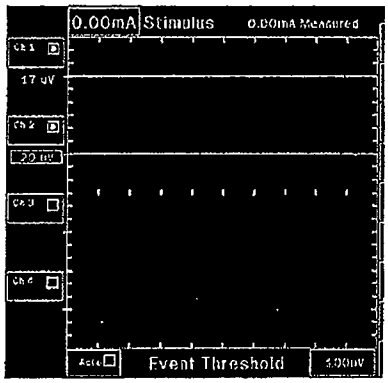
⚠ WARNING

AUDITORY AND VISUAL MONITORING ARE DISABLED WHILE MUTING IS IN EFFECT.

SOFTWARE SETUP

The NIM-Response front panel features a screen which displays EMG waveforms. The NIM-Response is operated by using touch-sensitive areas of the display screen.

MONITORING SCREEN



The MONITORING SCREEN displays EMG waveforms.

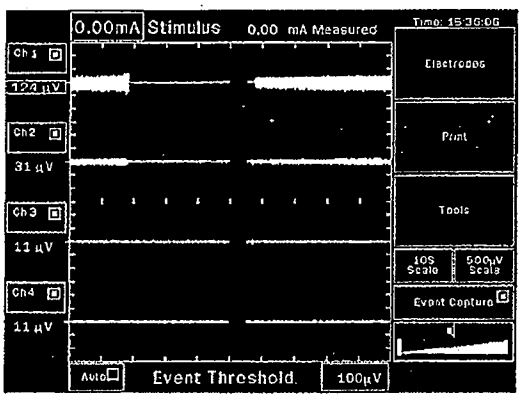
A STIMULUS FILTER indicates where the STIMULUS FILTER ends and real EMG data begins when using either a monopolar or bipolar stimulator connected to the NIM-Response.

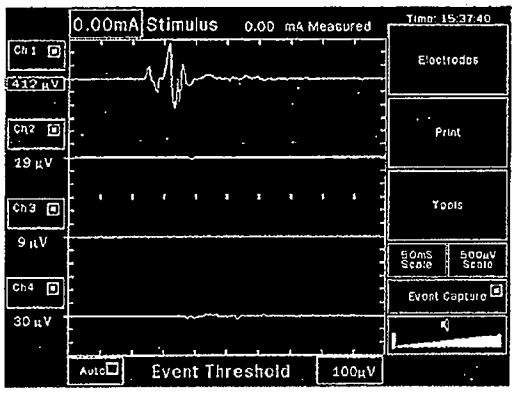
The touch-sensitive areas of the screen provide information and control by toggling between settings or displaying popup menus.

CHANNELS 1-4

Four channels can be monitored. During power-up, the NIM-RESPONSE automatically turns ON each channel that has an electrode connected from the patient to the Patient Interface. Pressing the CHANNEL button toggles the corresponding channel ON or OFF.

TIME SCALE INDICATOR AND CONTROL





The 50 mS TIME SCALE is the Power Up default. The 50 mS TIME SCALE graphs a detailed view of the data and is most effectively used to view a captured event or the detail for baseline or non-stimulated activity. When EVENT CAPTURE is ON, the screen will display the detail of the last event captured until a new event occurs. When EVENT CAPTURE is OFF, the screen displays a slightly undulating line until an event over the threshold level occurs; then, that event appears only briefly on the display.

The 10 S TIME SCALE, which resembles a histogram, graphs the maximum amplitude excursion of the 50 mS TIME SCALE sample, not just events above the EVENT THRESHOLD setting. That is, each vertical bar (one pixel column) in the 10 S TIME SCALE represents a sample which can be expanded in the 50 mS TIME SCALE.

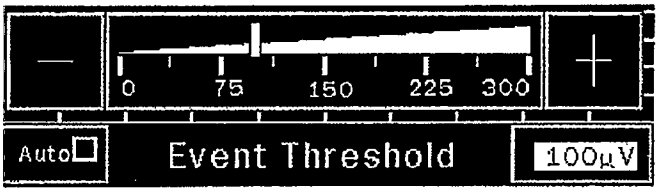
The 10 S TIME SCALE is useful for visualizing recent baseline EMG levels of active channels and the STIM Marker to show Stimulus activity. When EVENT CAPTURE is ON and an event over the threshold setting occurs, the Tone audio (if selected) will sound. The NIM-Response continues to take readings and display the ongoing data in the 10 S TIME SCALE.

EVENT THRESHOLD

Any EMG activity that exceeds the EVENT THRESHOLD is defined as an event. The event is heard as a beep called an EVENT TONE. When EVENT CAPTURE is ON, these event waveforms are displayed until replaced by the next event. The EVENT THRESHOLD is adjustable from 20 µV to 2500 µV. The default EVENT THRESHOLD is 100 µV.

Under certain circumstances, the default value of 100 µV may not be significantly greater than the baseline activity; therefore, it may be too sensitive. In this case, the EVENT THRESHOLD may be adjusted to reflect a more appropriate setting.

To adjust the EVENT THRESHOLD setting, press the button indicating the present setting. The setting will flash. The setting can then be adjusted by either touching the graphical scale or touching the "+"or "-" buttons . The new setting is indicated on the setting button while it is being adjusted and is also indicated by the relative position of a small vertical bar on the relative scale.



Event Threshold Setting Control

AUTO EVENT THRESHOLD

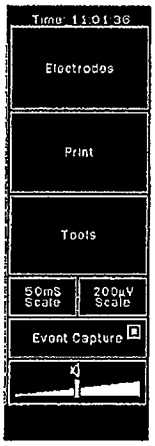
In a situation where the EMG has been elevated for a few seconds, the EVENT TONES (beeps) stop being helpful and simply become noise. The NIM-Response can automatically adjust the EVENT THRESHOLD to maximize information from the EMG and minimize unnecessary noise. The EVENT THRESHOLD is a filter that brings more significant events to the surgeon's attention while hearing the raw EMG from less important ones. The AUTO EVENT THRESHOLD can help the surgeon use the most sensitive settings possible.

The AUTO button is next to the EVENT THRESHOLD setting and has a square to indicate whether it is selected. The default is OFF.

The EVENT THRESHOLD remains the same for all channels until part of the baseline of an active EMG channel increases above the EVENT THRESHOLD for more than 5-10 S of numerous event tones sounding. When detected "BASELINE INCREASED" is announced the EVENT THRESHOLD of each effected channel is adjusted relative to it's baseline, and the text "AUTO" flashes. The AUTO EVENT THRESHOLD setting of each channel is displayed on the right hand side of the screen. Raw EMG from each channel is still audible.

The threshold automatically tracks an increasing or decreasing baseline, announcing "BASELINE INCREASED" for each significant further increase. If the baseline value decreases, the auto EVENT THRESHOLD resets at a lower value, until the setting reaches manual setting of the EVENT THRESHOLD. At that time, "Baseline Decreased" is announced, the text "auto" stops flashing.

MEASUREMENT CURSOR



With Event Capture on, touching a point of a wave form causes a pop-up box to appear on the screen. The voltage amplitude and time from zero (known as latency) are displayed.

CALIBRATING THE TOUCH SCREEN

When the touch screen seems to respond in an unexpected manner, it may be necessary to calibrate the Touch Screen. This happens because the Touch Screen registers the press in the wrong place on the screen. Examples of this are the Touch Screen failing to respond or responding erratically.

To calibrate the Touch screen, turn the power of the NIM Response OFF and back ON again. When the Xomed NIM-Response Splash Screen appears, press the Touch Screen until prompted to remove your finger; press Touch Screen Calibration. Next, a prompt is displayed to touch the lower left corner and the upper right corner of the screen. Finally, a prompt is displayed to touch the center of a circle appearing in the upper right corner of the screen. If the touch is not registered in the center of the circle, the sequence must be repeated. When the Touch screen completes the calibration, the NIM-Response enters its normal operating mode.

DEFAULTS

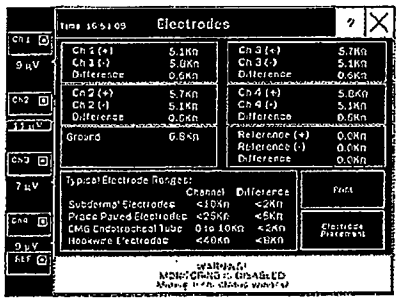
Setting	Default	Other Options
Channel 1-4 and Reference Channel	Auto	Manual
Time Scale	50mS	10S
Vertical Scale	500µV	200µV,2000µV
Stimulus	0.00mA	0.01mA to 3.00mA
Event Threshold	100µV	20µV to 2500µV
Auto Event Threshold	Off	On
Event Capture	On	Off
Volume	50%	0-100%

MAIN MENU

The Main Menu is displayed on the right-hand side of the screen while the unit is in monitoring mode. The Main Menu allows the user to adjust many of the software features.

ELECTRODES

ELECTRODES displays the impedance of electrodes and difference of their impedances for Channel 1 through 4 electrodes, as well as Ground and Anode electrodes. While the ELECTRODES screen is displayed, monitoring does not occur and the speaker is muted. The words "WARNING! MONITORING IS DISABLED" blink in reversed text to alert the user. After 30 Seconds, the *MUTING* voice is heard.

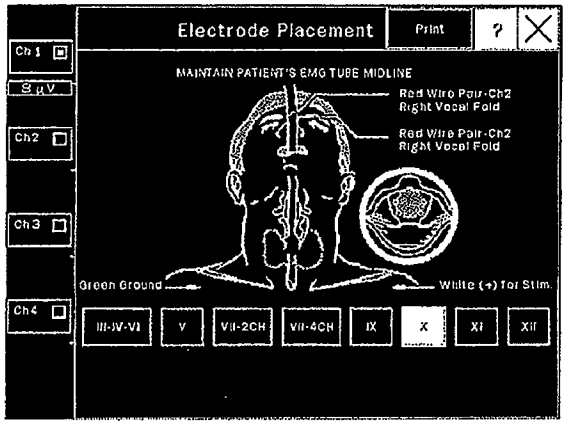


Electrodes

ELECTRODE PLACEMENT

ELECTRODE PLACEMENT displays the electrode placement to monitor cranial motor nerves by touching the corresponding cranial nerve number. Monitoring continues in the background while these menus are displayed.

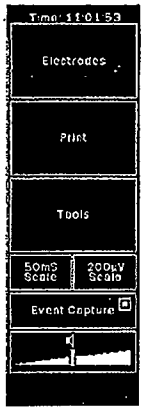
Press the Cranial Nerve number and electrodes appear. The exact placement of electrodes is based on the physician's knowledge of the procedure and the Cranial Nerves that are to be monitored during the procedure.



PRINT / SAVE

PRINT sends the screen displayed to the printer.

TOOLS



TOOLS button allows access to advanced features of the NIM-Response.

CUSTOMIZE MENU

CUSTOMIZE provides menus used to configure many of the NIM-RESPONSE features.

QUICK SETUP MENU

QUICK SETUP menu provides the ability to create and select surgeon or procedure preferences for feature controls and settings.

QUICK HELP

After selecting QUICK HELP, pressing any feature on the Main Monitoring Screen displays an explanation of that feature.

TIME SCALE

TIME SCALE toggles between two different display time scales: 50 mS and 10 S. Selection is displayed on the right middle portion of the screen in the main menu.

VERTICAL SCALE

VERTICAL SCALE selects the range of the EMG data display from 200, 500 or 2000 µV scale. Selection is displayed on the right-middle portion of the screen in the main menu. Changing the VERTICAL SCALE only affects the way the data is presented on the screen. It does not modify the sensitivity of the unit.

Verticle Scale Indicator and Control

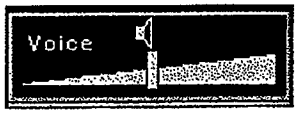
EVENT CAPTURE

EVENT CAPTURE displays on the 50 mS screen any EMG activity that exceeds the EVENT THRESHOLD. This waveform is displayed until it is replaced by the next event. Touching the EVENT CAPTURE turns this feature ON and OFF.

VOLUME

The VOLUME control adjusts the speaker. Upon Power Up, the VOLUME is automatically set at a moderate level. VOLUME cannot be turned completely OFF.

VOLUME is adjusted by touching the graphical volume scale. The setting is indicated by relative position of a small vertical bar.

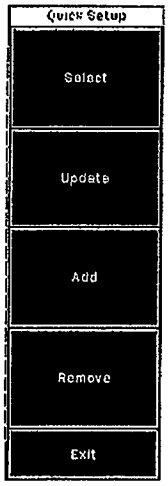


Volume Control

REFERENCE CHANNEL

REFERENCE CHANNEL is used as an additional means of artifact determination. The REFERENCE CHANNEL compares active EMG channels to a neutral or "reference" channel. When activity on the REFERENCE CHANNEL is detected greater than EVENT THRESHOLD at the same time there are Events on an EMG channel the "REFERENCE ACTIVITY" is detected and is announced. Place the two REFERENCE CHANNEL electrodes in a muscle not affected by manipulation of the nerve being monitored. For example, when monitoring the right facial nerve, the reference electrodes could be placed in the left obicularis oris muscle. Activity on the REFERENCE CHANNEL may be from other equipment causing interference. It may also may be from global evoked or spontaneous neuro motor activity like the patient becoming light.

QUICK SETUP MENU



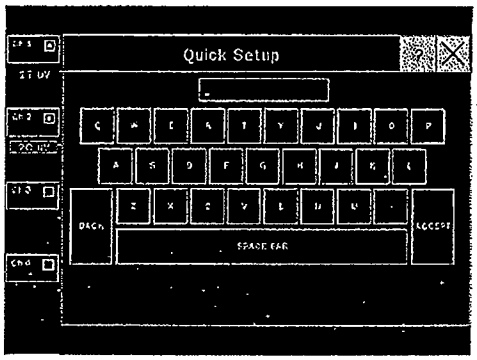
Quick Setup Menu provides access to configuration of features. The settings configurations can be modified in the following ways: SELECT, UPDATE, ADD, and REMOVE.

SELECT

Quick Setup configurations can be chosen by pressing SELECT. A list of stored settings is displayed. Press the configuration and then press SELECT. The active Quick Setup configuration is displayed on the SELECT button of the Quick Setup Menu.

UPDATE

To UPDATE an existing configuration, verify the configuration that is active (which is displayed on the SELECT button of the Quick Setup Menu). Adjust feature settings such as Stimulation, Event Threshold, Event Capture and then press UPDATE. This saves these settings of this Quick Setup configuration.



ADD

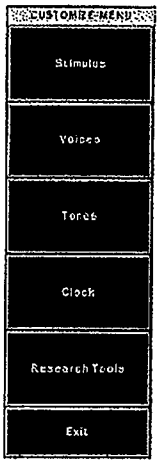
To ADD configurations preferred by the surgeon, adjust feature settings such as Stimulation, Event Threshold, Event Capture and then press ADD on the Quick Setup Menu. A keyboard is displayed to allow the entry of the name of the physician or the procedure configurations. Press Accept to save these settings under the name that was typed. Pressing "X" exits this interface without saving.

REMOVE

Quick Setup configurations can be deleted by pressing REMOVE. A list of stored settings are displayed. Select the setting to be removed and then press REMOVE.

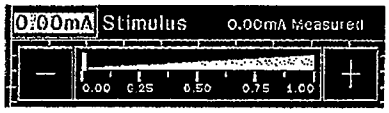
CUSTOMIZE MENU

CUSTOMIZE is used for modifications to the listed features. The NIM-Response continues monitoring while settings on the configuration menus are being changed.



STIMULUS

The STIMULUS appears at the top left corner of the display and controls the stimulating current delivered by stimulator probes when connected to the NIM-Response. The range of output is 0.0 to 3.0 mA. While below 0.10 mA the setting is adjustable by increments of 0.01 mA; while above 0.10 mA, it is adjustable by 0.05 mA. The default STIMULUS setting is 0.00 mA.



Stimulus Setting Control

To adjust the STIMULUS intensity, press the setting button. You see the setting flash. The setting can then be adjusted by either touching the graphical scale or touching the "+" or "-" buttons. The new setting is indicated on the setting button while it is being adjusted and is also indicated by the relative position of a small vertical bar on the relative scale.

The MEASURED value, which appears in the top right corner of the display screen, reflects the amount of stimulating current "flowing through the patient" and should approximate the STIMULUS value is displayed in milliamps (mA). The MEASURED value may fluctuate between 0.00 mA - 0.05 mA until contact is made by a probe.

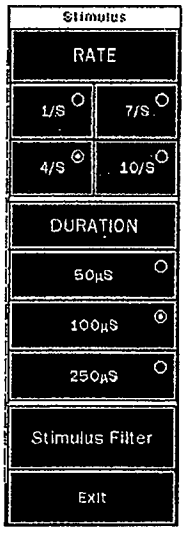
Stimulus Submenu

STIMULUS RATE

The rate of stimulation is adjustable. The stimulus pulse can be delivered at a rate of either 1/S, 4/S, 7/S, or 10/S. The default rate is 4/S.

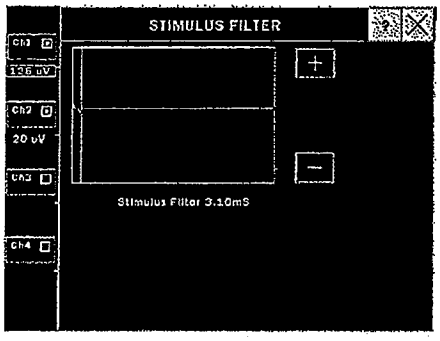
STIMULUS DURATION

The duration of stimulation is adjustable. The stimulus pulse lasts either 50 µS, 100 µS, or 250 µS. The default duration is 100 µS.



STIMULUS FILTER

STIMULUS FILTER displays a window showing where the stimulus artifact delay ends and real EMG data begins. The STIMULUS FILTER can be set for values of: 1.00 mS, to 4.10 mS. The default is 3.10 mS.



DEFAULTS

Setting	Default	Other Options
Stimulus Rate	4/S	1/S, 7/S, 10/S
Stimulus Duration	100µS	50µS and 250µS
Stimulus Filter	3.10mS	1.00 to 4.10mS

Voices Submenu

The VOICES controls the voices produced by the NIM-Response as follows:

HELP VOICES

Audible HELP voices can be turned ON or OFF via the Voices submenu. When the HELP voices are turned ON, you can select specific voices. When the HELP voices option is turned OFF, all help voices are OFF.

Check Electrode Voice

When an electrode is not detected, the "CHECK ELECTRODE" alarm sounds. This could be due to electrode not placed, electrode falling out of patient, the electrode not properly seated in the Patient Interface, or a defective electrode. When this voice is turned OFF, only the Bleedle alarm sounds.

Muting Voice

While the electrocautery is in use, the MUTING voice and Bleedle alarm sounds after 30 Seconds of use, and the Bleedle alarm repeats every 30 Seconds thereafter.

STIMULUS VOICES

STIMULUS VOICES can be configured as SETTING, "STIMULUS," TONE, or OFF. The default is STIMULUS VOICE set to ON and SETTING selected.

Stimulus Voice

The stimulus voice verifies delivery of current to the surgical field.

Setting Voice

The SETTING VOICE announces the value of the STIMULUS. It also announces the new stimulus setting when it is adjusted. Example: 0.50 mA is announced as "Point Five".

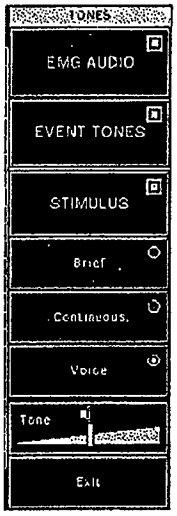
Tone

Stimulus delivered through the probe to the surgical field is confirmed by a tone.

DEFAULTS

Setting	Default	Other Options
Help Voices	On	Off
Check Electrode	On	Off
Muting	On	Off
Stimulus Voices	On	Tone
Setting	Off	On
Stimulus	On	Off
Tone	Off	On
Volume	20%	10-100%

Tones Submenu



The TONES submenu controls the raw audio and tones produced by the NIM-Response. The EMG Audio and EMG Tones cannot be turned OFF simultaneously.

EMG AUDIO

The EMG Audio can be turned ON or OFF. When it is ON, EMG activity can be heard as a static-like grinding sound. The volume can be turned up or down using the Volume Control keys. When it is OFF, the EMG audio cannot be heard. The default setting is EMG audio on.

EVENT TONES

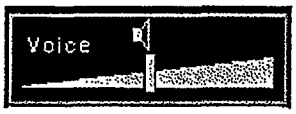
The Event Tones can be turned ON or OFF. When it is ON, an EMG event above the set EVENT THRESHOLD is heard as a beep tone. The tone reflects on which channel the event occurred. A lower pitched beep represents Channel 1; a higher pitched beep represents Channel 2, and so on through Channel 4.

STIMULUS WARBLE TONES

The STIMULUS WARBLE TONE sounds whenever electrical current is being delivered to the surgical field, through the stimulus probe that is greater than 80% of the set current. The current delivered TONE or VOICE is not active below .05 mA. The duration of the STIMULUS TONE is adjustable as follows: OFF, BRIEF, CONTINUOUS, OR VOICE.

TONE VOLUME

May be set by touching along the graphical volume control bar, with FULL volume to the far right.



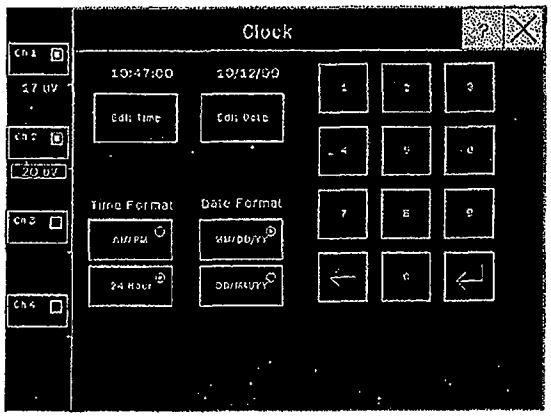
Volume Control For Event Tones

DEFAULTS

Setting	Default	Other Options
EMG Audio	On	Off
EMG Tones	On	Off
Stimulus	Brief	Continuous, Voice
Tone Volume	0.30	0.10 – 1.00

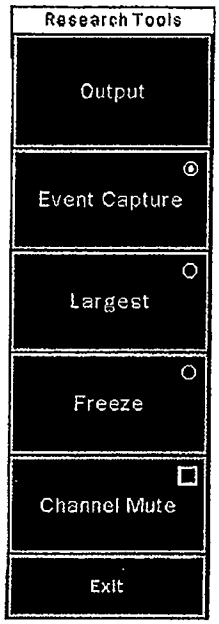
Clock Submenu

The CLOCK submenu allows the correct time and date to be entered into the NIM-Response. Time is displayed in 12 hour and 24 hour formats. The date format is U.S. (mo/day/yr) or CO (day/mo/yr) with leap year compensation valid up to 2100.



Clock Adjustment Window

Research Tools Submenu



OUTPUT MENU

The Output Menu is used to select whether information is documented to a HPGL compatible printer, LS120 SuperDisk drive, or a ZIP drive. The information is formatted according to Output. Menu selections are sent to the Printer/Data Output on the back panel of the NIM-RESPONSE.

EVENT CAPTURE

When the EVENT CAPTURE button on the Main Menu is ON, it holds each Event on the screen until it is replaced by the next Event. When EVENT CAPTURE is OFF, the current EMG activity waveform is displayed.

LARGEST

LARGEST displays each EVENT as it occurs and at the end of a series of events, displays the LARGEST of these waveforms. The screen continues to display each EVENT and holds the LARGEST at the end of the series of Events.

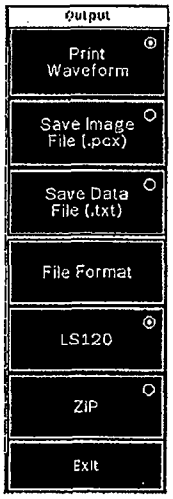
FREEZE

When Freeze button on the Main Menu is turned ON, it will hold the waveform until Freeze is turned OFF. When Freeze is OFF, the current EMG activity waveform is displayed.

CHANNEL MUTE

When channel mute is selected, a speaker icon appears with each selected channel. Pressing the channel select button cycles through channel on, channel mute (speaker icon blank), and channel off.

OUTPUT



DEVICE

When Printer is selected, the "Print" button is displayed on the main menu. The default device is Printer.

When either the LS120 or the ZIP is selected, the "Print" button becomes "SAVE IMAGE" or "SAVE DATA", depending on the format selection. When the unit is in the process of saving, the button will display either "SAVING IMAGE" or "SAVING DATA."

FORMAT

The FORMAT of information saved to disk can be either an IMAGE file or a DATA LOG. The IMAGE file is stored in PCX format. The DATA LOG file contains the time and X and Y data in an ASCII comma delimited format. The default FORMAT is IMAGE.

DEFAULTS

Setting	Default	Other Options
Output Device	Printer	LS 120, Zip
View	Event Capture	Largest, Freeze
Measurement Cursor	Off	On
Channel Mute	Off	On

2 • USING THE NIM-RESPONSE

ANESTHESIA REQUIREMENTS

All decisions regarding anesthesia are the responsibility of the attending licensed medical practitioner administering the anesthesia. Because all intraoperative monitoring discussed in this User's Guide requires that EMG activity be recorded from a muscle or muscles, it is important that the muscle(s) not be paralyzed during the surgery or at least during those parts of the surgery when the nerve(s) being monitored is (are) deemed at risk by the surgeon. It is important that the surgeon discuss these issues preoperatively with the attending licensed medical practitioner administering the anesthesia.

⚠ WARNING

THE USE OF PARALYZING ANESTHETIC AGENTS WILL SIGNIFICANTLY REDUCE, IF NOT COMPLETELY ELIMINATE, EMG RESPONSES TO DIRECT OR PASSIVE NEURAL STIMULATION.

ELECTRODE SELECTION

When selecting recording electrodes, the following questions should be considered:

- What muscle group (s) is (are) being monitored?
- How will the electrodes be secured?
- Is subdermal or intramuscular placement more appropriate?

There are several electrode styles available for monitoring electromyography. You may need to try different types to determine a preference.

ELECTRODE PLACEMENT

Electrode placement should be performed by or under the direction of a licensed medical practitioner. Areas of electrode insertion should be prepped by vigorous cleaning with an alcohol wipe. Usually, recording electrodes are placed before the sterile field is draped and defined. Never let electrode leads contact one another.

The exact location for the electrodes is defined relative to the surgical procedure being monitored. For all facial nerve monitoring, the patient ground electrode may be located on the patient's upper chest (sternum). The placement for the anode (+) electrode for the monopolar stimulating probe is on the ipsilateral shoulder.

Once the electrodes have been placed and secured with tape, the connector end may be inserted into the input jacks on the PATIENT INTERFACE BOX.

⚠ WARNING

TO AVOID EYE INJURY DURING ELECTRODE PLACEMENT, THE ELECTRODE NEEDLES SHOULD BE DIRECTED AWAY FROM THE ORBIT WHEN INSERTED FOR ORBICULARIS OCULI MONITORING.

STIMULATOR PROBE CONNECTION

The cable on a MONOPOLAR STIMULATOR PROBE plugs into the black cathode (-) stimulus jack on the PATIENT INTERFACE BOX. Since the stimulator probe and cable must be sterile for surgical applications, the stimulator may be connected at the beginning of the procedure in the event the PATIENT INTERFACE BOX is not accessible later on in the case.

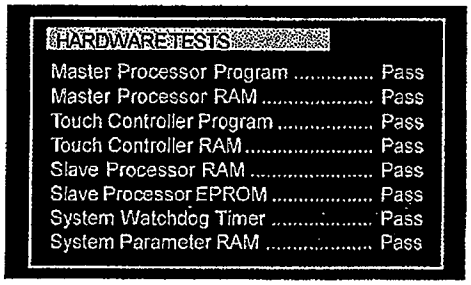
The surgeon should test probe for current delivery as soon into the case as possible. This is done by selecting a "stimulus intensity" on the NIM-Response front panel (greater than 0.00 mA) as indicated on the STIMULUS mA portion of the screen. An intact circuit results in corresponding numbers approximating set amount in the MEASURED mA portion of the screen.

SYSTEM CHECKS AND TESTS

These checks and tests should be performed for every case before the NIM-Response is connected to the patient.

POWER UP TESTS

An internal integrity check is automatically performed each time the system is turned ON. You see a series of messages on the display screen. The software version number and revision date are displayed briefly, then the NIM-Response does a series of self-tests on the hardware.


HARDWARE TESTS
Master Processor Program ..... Pass
Master Processor RAM ..... Pass
Touch Controller Program ..... Pass
Touch Controller RAM ..... Pass
Slave Processor RAM ..... Pass
Slave Processor EPROM ..... Pass
System Watchdog Timer ..... Pass
System Parameter RAM ..... Pass

Hardware Test Results

If any self test fails, call MEDTRONIC XOMED U.S. Customer Service toll-free at 1-800-874-5797. If you are outside the United States, contact your local MEDTRONIC XOMED representative. If a problem is found with the microprocessor, the NIM-Response immediately returns to the second start up screen and indicate a microprocessor failure. No more monitoring can take place.

ELECTRODE IMPEDANCE CHECKING

Ensure that all electrodes are adequately connected to the patient and to the NIM-Response before surgical drapes are in place. The NIM-Response has an impedance meter to perform this test. Display the ELECTRODES screen to access the impedance test.

The impedance for each individual electrode is shown with the resulting difference between the positive and negative electrodes for each channel. The greater the difference between the positive and negative electrodes on any one channel, the greater the possibility that there may be unwanted background noise present on that channel.

Typical impedance values are as follows:

- Prass Paired EMG Electrodes ..... 25 kΩ or less
- Subdermal needle electrodes ..... 10 kΩ or less
- Hookwire electrodes ..... 40 kΩ or less
- Endotracheal ..... 10 kΩ or less
- Paired subdermal ..... 20 kΩ or less

The difference in impedance between the positive (+) and negative (-) of a channel should be less than 10 - 20% of the lowest channel impedance. Press the "x" in the upper-right hand corner to return to the monitoring screen.

QUICK SETUP

At power-up, QUICK SETUP settings are displayed along with the statement, "Select Physician Initial Settings". These settings may need to be adjusted as the surgery progresses. Any of the saved Physician Settings may be selected, however if no selection is made within 10 Seconds, the settings of the highlighted names are activated. The main monitoring screen is then displayed. Verify that the STIMULUS and EVENT THRESHOLD values the physician desires are set.

CHECK ELECTRODE ALERT

During power-up, the NIM-Response automatically turns ON each channel that has an electrode connected from the patient to the PATIENT INTERFACE BOX. When no electrodes are plugged into the PATIENT INTERFACE BOX, the NIM-Response warns you in 20 S that an electrode lead is not making proper electrical contact (OFF). You then hear the Bleedle Alarm. The channel button flashes continuously until the electrode is placed or the channel is turned OFF. The electrodes screen is displayed showing which electrodes are OFF.

The NIM-Response checks all the electrode leads every 1/2 S during MUTING and ELECTRODES CHECK by sending 60Hz pulses through the leads. It reads the impedance of each lead and verifies that the readings are within normal range.

When the electrode impedance levels are too high, MUTING turns on and the "CHECK ELECTRODES" Bleedle Alarm sounds. The indicator light of the affected channel flashes. The ELECTRODES screen is displayed and indicates which electrodes are outside of normal operating range or "OFF".

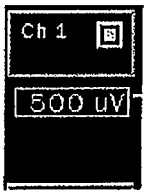
MUTING ALERT

When the NIM-Response stays in Mute mode for more than 60 S (except during an ELECTRODES CHECK), the MUTING alarm sounds to warn that there is no ongoing acoustic or visual monitoring. The message "WARNING: MONITORING IS DISABLED" flashes on the screen. Alarms repeat every 60 S until the NIM-Response exits Mute mode.

ADJUSTING THE EVENT THRESHOLD

BASELINE ACTIVITY

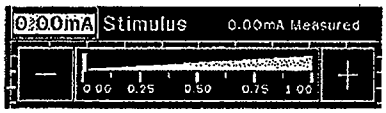
Typically, when the nerve to be monitored is not being electrically stimulated or manipulated by the surgeon, there is little or no EMG activity detected. Therefore, the magnitude of the on-going 'quiet baseline' signals may be quite small. These signals may be 30 µV or less and are shown on the left side of the screen near the appropriate channel microvolts (µV) only when Event Capture is Off. If Event Capture is On, the microvolts (µV) will reflect the amplitude of the last event on the channel (s) being monitored.



Peak-to-Peak Voltage Reading

SETTING THE STIMULUS LEVEL

Press the STIMULUS setting button in the upper left corner to adjust the stimulus output to the desired level. The stimulation level is displayed on the button.



Stimulus Control and Indicator

At present, there is no complete agreement on the optimal level for facial nerve stimulation (Beck and Benecke, 1990). The absolute stimulus intensity required to adequately stimulate any cranial motor nerve is determined by a complex combination of several factors including (but not limited to) the following:

- The functional health of the nerve itself
- The type of stimulation probe used (monopolar or bipolar)
- How well the stimulator probe makes contact with the nerve
- Whether cerebral spinal fluid is covering the nerve, etc.
- The duration of the stimulus

You may want to use the smallest amount of stimulus necessary to elicit a detectable EMG event. Typically, stimulus current levels of 0.3 mA are high enough for adequate direct monopolar stimulation of the facial nerve. The best guideline for setting the stimulus intensity level is to use the lowest amount of stimulation that produces an EMG response large enough for monitoring.

WHEN ELECTROCAUTERY AND CUSA ARE USED

When the electrocautery is in use, the NIM-Response mutes. After 60 seconds of muting due to electrocautery, you hear "MUTING" and "WARNING: MONITORING IS DISABLED" is displayed. The bleedle alarm sounds every 60 seconds.

Whenever electrocautery is in use or is in the standby mode, the electrocautery tip should be isolated from the NIM-Response stimulator probe and electrodes.

When CUSA (cavitron (ic) ultrasonic aspirator) is in use, effective monitoring cannot take place. The baseline may rise on one or both channels to 200-500 µV. You may compensate by adjusting the Event Threshold up and then down after the CUSA is off. The baseline may still linger at 40-80 µV. However, an increase in the baseline right after use of CUSA may indicate nerve irritation.

Another example of when prolonged muting might occur is when a radio-frequency signal of unknown origin occurs in the surgical environment without the knowledge of the surgical team.

UNDERSTANDING WHAT YOU HEAR

EMG ACTIVITY

The TONE MENU is used to select whether EMG AUDIO, EVENT TONES, or both are audible. Both EVENT TONES and EMG AUDIO can be ON at the same time, but both features cannot be simultaneously disabled.

The EMG AUDIO signals are not influenced by the EVENT THRESHOLD. Therefore, all EMG activity, regardless of amplitude, is audible when the EMG AUDIO is ON. The EMG activity may sound like a low-pitched drumbeat at times. When two channels are monitored at the same time, it is unlikely that you will be able to differentiate the EMG signals as to their channel of origin strictly by the sounds they produce.

EVENT TONES, however, is coded to distinguish the channel of origin. Only signals with amplitudes exceeding the EVENT THRESHOLD produce a tone.

The tone for Channel 1 activity is lower in pitch than the Channel 2 tone and so on for channels 3 and 4. This lets you tell by the tone's pitch which channel is involved. When EMG activity exceeding the event threshold occurs at the same time on both channels, only one of the tones sounds.

VERIFYING STIMULUS DELIVERY

The NIM-Response allows you to verify delivery of current both audibly and visually.

There may be times when the surgeon has placed the probe into the surgical field expecting an EMG response and none is evoked. When this occurs and the nerve has functional intergrity and was properly stimulated, you must check that a stimulus current was actually delivered to the field.

One of the features of the NIM-Response is the STIMULUS Tone option which is selected from the TONES MENU. When stimulus is delivered but no events are evoked, the STIMULUS WARBLE TONE indicates that current has been delivered to the surgical site. EVENT TONES override STIMULUS TONES. This can be set to BRIEF, CONTINUOUS, VOICE, or OFF.

Stimulus delivery can be visually confirmed by comparing the STIMULUS and the MEASURED readings. The MEASURED reading is found on the upper right-hand side of the screen next to STIMULUS. The value should be approximately the same as the STIMULUS SETTING.

RECOGNIZING ARTIFACT

The NIM-Response features sophisticated artifact rejection technology designed to provide highly sensitive and accurate monitoring. The technology encompasses electrocautery detection, overload detection, and stimulus artifact rejection associated with the stimulating MONOPOLAR probes. The signals associated with these conditions are automatically muted and will not be heard.

However, there may be electrically generated signals in the range of true responses that cannot be differentiated by the NIM-Response. For example, a transcutaneous stimulator used by the anesthesiologist might generate an audible signal. Another example would be any external nerve locator/stimulator not synchronized with the NIM-Response. Another possible source of electrical signal is electrical leakage from faulty thermal cautery units. You can identify the spurious signals by their lack of surgical context. That is to say, there was nothing the surgeon was doing at that moment that could have caused a true EMG response.

Another artifact signal that can be erroneously interpreted by the NIM-Response as an EMG event can occur when the surgeon strikes two metal instruments together within the surgical field, such as striking a metal suction tube with a dissecting tool. Such signals are typically monophasic with fast onset and offset. That is, the signals appear on the screen as sharply peaked responses in one direction only.

While these artifacts are significantly different in waveform appearance from true EMG events (which have a biphasic waveform), the magnitudes of these signals can reach several hundred microvolts, exceeding the EVENT THRESHOLD. Therefore, this can cause the EVENT TONE to sound. This type of artifact cannot be automatically detected and ignored by the NIM-Response. However, the surgeon is usually aware when two instruments have been struck together and can, therefore, relate such "false positive" responses to the surgical context.

INTERPRETING THE ALARMS

The alarms draw attention to any condition which prevents proper data acquisition. None of the audible alarms should be ignored. One must assume that valid monitoring has been halted, and determine immediately why the alarm sounded. There are three distinct alarms:

BEEP ALARM

The high-pitched, repetitive beep is used to register failure of internal microprocessor hardware. When you hear it at any time other than at Power Up, stop using the NIM-Response System and contact MEDTRONIC XOMED Customer Service at 1-800-874-5797.

BLEEDLE ALARM

This is a three-note alarm (BLEE-dle DEET) that cannot be disabled. It repeats until the responsible condition is remedied. This alarm is heard when:

- A recording electrode lead is off (repeats every 20 Seconds).
- The NIM-Response System has been in MUTE mode for more than one minute (unless you are in ELECTRODE CHECK). Repeats about once per minute.

VOICE ALARM

Several context specific voice alarms are available. A relevant message is simultaneously displayed.

WHEN THE CASE IS COMPLETE

Before closing the surgical site, the surgeon should evaluate the nerve's functional integrity one more time. This should be done by stimulating the nerve both proximal and distal to the immediate dissection area as far as is accessible within the surgical field. Use the lowest level of stimulation that produces a response.

Continue to monitor with the NIM-Response System throughout the procedure (until the incision is closed), since items such as wound dressings might exert stress or pressure on the nerve and affect its function.

WHEN MONITORING IS COMPLETE

Turn OFF the power to the NIM-Response System when the entire procedure is completed, and have the Licensed Medical Practitioner remove the electrodes from the patient.

The disposable Prass Monopolar Stimulator Probe and patient electrodes must be discarded after surgery.

Wipe the PATIENT INTERFACE CABLE and the MUTING PROBE CABLE, and visually inspect them for cracks and other damage. If they are damaged, return them for service.

3 • TROUBLESHOOTING

SYMPTOM	CAUSE	SOLUTION
No visual display or audio alarms at power-up.	Power cord not connected to outlet or to the NIM-Response system. Power switch not turned on.	Plug in power cord. Turn power switch on.
Touching the screen changes has unexpected results.	Touch screen out of calibration.	Turn unit off, then press the screen until the screen calibration test is displayed. Follow the instructions on the screen to recalibrate.
Electrode impedance is too high. >10KΩ for subdermal electrodes >25KΩ for Prass Paired electrodes >10KΩ for EMG Tube >40KΩ for hookwire electrodes	Electrode dislodged from patient, but not completely out. High resistance in electrode. Electrode pin not firmly inserted into patient interface.	Insert dislodged electrode; tape down in place. Remove and replace with new electrode. Check connection at Patient Interface box.
Electrode impedance Ω 0.0KW.	Positive and negative electrodes touching below surface of skin. Extremely low impedance, particularly in EMG tubes.	Remove and relocate electrodes. Use "tap test" near electrodes to evoke EMG or artifact. If activity is noted on channel in question, proceed.
Channel button is flashing. Electrode reading is "--- KΩ" or "OFF."	Electrode laying on skin surface. Electrode placement insecure. Dirty electrode tip. Electrode cable broken. Electrode pin disconnected from patient interface.	Re-insert electrode in question. Remove and replace electrode in question. Check connection to Patient Interface box.
Electrode difference is greater than 2KΩ (subdermal electrodes) or 10KΩ (Prass Paired electrodes).	Dirty electrode. Mismatched pair. Unequal placement.	Remove and replace electrode for appropriate channel with highest impedance reading first. Remove and replace electrode in question.
Electrosurgical interference.	Muting Probe not connected. Muting Probe input insufficient. Electrosurgical grounding inadequate. Source of interference unidentified. NIM-Response system or Patient Interface cable too close to ESU or its cables.	Check Muting Probe connections. Move input to "MORE MUTE". Check electrosurgical grounding pad on patient Identify source of interference; then eliminate or separate from the NIM-Response system. Maintain separation between electrosurgical cable and the NIM-Response system. For less coupling, coil up the Muting Probe next to the NIM-Response system.
Interference on anesthesia equipment.	Lead checking current near anesthesia electrodes.	Anesthesia try alternate electrode channel. Turn stimulator to 0.0mA when not stimulating.
Excessive muting.	Unit receiving excessive signal into the Muting Probe or electrode leads.	Move the Muting Probe connector to a lower number unit until it stops muting. If it still mutes in position "1," disconnect the muting detector completely.

SYMPTOM	CAUSE	SOLUTION
Inadequate muting.	Signal from ESU is inadequate to cause muting.	Move the Muting Probe connector to a higher number until it mutes. If it still does not mute in position "4," loop the ESU cable and clip the muting detector over the doubled cable.
No response to direct stimulation.	Inadequate stimulus intensity.	Increase stimulus intensity.
	Paralyzing anesthetic in use.	Eliminate paralyzing anesthetic.
	White stimulation (+) electrode has fallen out or is not connected.	Check that Stimulus Measure is approximately the same value as the Stimulus setting. Re-insert electrode in question. Secure all recording and stimulating electrode connections and check the impedance values.
	Probe not connected.	Check stimulator anode (+) and cathode (-) connections.
	Patient safety fuse blown.	Check fuse in Patient Interface box (32 mA. x 250V). Replace if necessary.
	Not holding probe on nerve long enough.	Hold probe tip to nerve for at least 1 S.
	Nerve not contacted.	Check stimulator tip for obstruction. Replace if necessary. Check location of stimulation.
	Volume control too low. Event threshold set too high.	Check and correct all settings: volume, event threshold, stimulus intensity.
	Excessive current shunting in surgical field.	Remove fluids from surgical stimulating area.
	No electrodes in innervated muscle. Nerve not stimulable.	Place channel electrodes in muscle to be monitored.
Unexpected responses when not directly stimulating nerve.	Unexplained continuous "train" EMG response.	Identify and eliminate possible source of "train" stimulation: Cold irrigation Laser heat Retraction on nerve or muscles being recorded. Patient waking from anesthesia Nerve drying Ultrasonic aspirator
	Nerve or monitoring area being stimulated or manipulated by thermal or mechanical means.	Identify and eliminate source of inadvertent manipulation.
	Metal-to-metal discharge artifact.	Determine response type from waveform pattern on 50 mS screen.
	Intertwined recording electrode and stimulator wires.	Disentangle recording electrode and stimulator cables.
	Inadvertent manipulation of electrode wires, Patient Interface cable, or recording area on patient.	Check area near recording electrodes for excessive stretching from tape, drapes, etc.
	Electrical interference from other equipment.	Check for intermittent stimulation from anesthesiologist (i.e., hand-held electrical stimulator). Move NIM-Response system away from source of interference. Make sure Patient Interface cable and electrode wires do not cross other electrical equipment or cables.

4 • MAINTENANCE AND SERVICE

This section of the User's Guide describes how to care for your NIM-Response and what to do when you have problems. Preventive maintenance does not require access to the interior of the instrument and may be performed by the technician/operator.

For the safe and warranted use of the unit, corrective maintenance and internal adjustments should be left to qualified MEDTRONIC XOMED service personnel.

PREVENTIVE AND CORRECTIVE MAINTENANCE

Preventive maintenance for the NIM-Response System consists of visual inspection, periodic cleaning and running a general checkout using the PATIENT SIMULATOR.

Follow the preventive maintenance schedule outlined below. Your own schedule may vary from this schedule based upon the type and amount of system use.

CLEANING THE NIM-RESPONSE SYSTEM

Remove dust on the outside of the instrument with a soft brush or cloth. Remove any remaining debris with a soft cloth that has been slightly dampened with alcohol.

VISUAL INSPECTION

Check the NIM-Response System occasionally for exterior damage. Only qualified MEDTRONIC XOMED service personnel should replace damaged parts.

AFTER EACH USE

Wipe the PATIENT INTERFACE CABLE, MUTING PROBE CABLE (S), and NIM-Response clean, and visually inspect for any damage.

Clean any substance from the PATIENT INTERFACE BOX, making sure that nothing is forced into the electrode connector sockets.

SERVICE AND REPAIR PROCEDURES

MEDTRONIC XOMED is committed to provide the highest standard of workmanship in manufacturing the NIM-Response System. Your NIM-Response requires a minimal amount of maintenance: however, MEDTRONIC XOMED recommends preventive maintenance and calibration scheduled at yearly intervals. The Mainframe Biomedical Verification Test Procedures should be performed at least annually and whenever a problem is suspected.

Comprehensive testing and calibration should be performed by returning the entire system, including the patient interface and muting probe to:

Medtronic Xomed Repair Department
6743 Southpoint Drive N
Jacksonville, Fl 32216

IF YOU SUSPECT A PROBLEM WITH THE NIM-RESPONSE

NOTE: When contacting our Customer Service and Technical Support, please have the appropriate product number, product serial number, date of purchase and nature of inquiry available.

Product Number _____

Serial Number _____

Date of Purchase _____

A system that is not functioning properly SHOULD NOT BE USED AT ALL until all necessary repairs have been made and the unit has been tested to ensure that it is functioning in accordance with published MEDTRONIC XOMED specifications.

To avoid negating the warranty, repairs should be performed by MEDTRONIC XOMED. You have sole responsibility for any malfunction resulting from improper maintenance or repair by anyone other than qualified MEDTRONIC XOMED personnel.

U.S. CUSTOMERS

Should your monitor or related equipment malfunction, MEDTRONIC XOMED provides, at no charge, loaner equipment shipped to your facility by UPS or Federal Express for use while your equipment is being repaired by MEDTRONIC XOMED. Please adhere to the following guidelines:

- When a loaner mainframe is ordered (REF 53-50001), please reuse the shipping material and carton when you return your monitor to MEDTRONIC XOMED. Insure the unit.
- When a loaner is not ordered, please package the monitor as safely as possible and insure.
- A return goods authorization number is not required on repairs. A copy of your purchase order is required. Make certain the purchase order includes the following:
    - Shipping and billing information
    - Purchase order number
    - Contact person
    - Phone number
    - Description of malfunction
    - Your MEDTRONIC XOMED account number
- Please indicate preferred method of return shipment. Otherwise the unit will be shipped back via UPS ground.
- When the malfunctioning unit is not covered by warranty, MEDTRONIC XOMED will contact your facility promptly with a repair cost estimate if requested. The customer will be responsible for freight charges on non-warranted units.
- When you have loaner equipment and you receive your repaired unit, please package the loaner equipment as safely as possible using the foam provided with your repaired equipment. Include paperwork indicating the unit is a loaner, and MEDTRONIC XOMED will credit your account.
- Loaner equipment not received by MEDTRONIC XOMED within 30 days from the date repaired equipment is shipped will be invoice at full purchase price.

THE PRINTER

The Printer, if purchased through Medtronic Xomed, should be returned directly to Hewlett-Packard for repairs or service. The Hewlett-Packard U.S. Customer Support phone number is (208) 323-2551. Additional telephone numbers, addresses, and other details may be found in the Hewlett-Packard Printer User's Manual shipped with the printer.

Concerns or question regarding second party printers should be directed to the respective manufacturer. Second party printers must comply with FCC Part 15.1B.

STORAGE

Always store the NIM-Response in a cool, dry place.

APPENDICES

APPENDIX A • GLOSSARY & QUICK REFERENCE TERMS

ampere

Unit of measure for electrical current. One (1) milli-amp will flow when one volt is connected across 1 K Ohm of resistance.

amplitude

Quantitative (microvolts) measurement of the peak-to-peak height of EMG response.

anode

The positive (+) pole or electrode of an electrical stimulator, remote needle in the case of a "monopolar" stimulator, and one of two poles on a bipolar stimulator. See *cathode.*

artifact

Any audio response or recorded visual display transmitted by the recording electrodes caused by something other than true EMG activity. See *stimulus artifact.*

baseline EMG activity

Ongoing, low level EMG activity (auditory and visual) elicited from the target muscle (s) at rest.

biphasic waveform

An EMG visual display with contiguous components which lie on either side (positive and negative) of the baseline. See *monophasic waveform.*

bipolar stimulation

Near-field (closely adjacent) cathode and anode contact to neural tissue and current delivery which minimizes current spread to other structures or tissue. Recommended for specific identification of close proximity of neural tissue (s).

burst response

Asynchronous, non-evoked response.

cathode

The negative (-) electrode of an electrical stimulator circuit. The NIM-Response deliver stimulating current in the cathode-to-anode (negative-to-positive) direction.

constant current stimulation

Electrical stimulation which is controlled by the amount of current desired at the site of stimulation independent of the electrode (stimulator) impedance characteristics.

constant voltage stimulation

Electrical stimulation controlled by setting the voltage which delivers unknown levels of current, dependent upon electrode (stimulator) impedance characteristics.

current

The movement of electrons through a conductor. It is measured in milli-amperes by the NIM-Response.

current jumping
When stimulating current travels across tissue being stimulated to adjacent tissue not being directly stimulated. Can be the cause of "false positive" responses.

current shunting
When stimulating current shunts or escapes away from the targeted nerve to fluid (CSF, blood or irrigant) in the surgical/stimulating field. Can be the cause of "false negative" responses.

CUSA
Cavitron (ic) Ultrasonic Aspirator

DC offset
Excessive charge on the patient resulting from electrosurgical activity without proper patient grounding. The presence of DC offset interferes with monitoring since the voltage levels of DC offset are generally greater than the EMG readings. DC offset can be recognized by its characteristic slope upward or downward.

default setting
The automatic setting determined at the factory or achieved at Power Up.

depolarization/repolarization [of a nerve]
The initiation and reaction of the firing of a nerve. The positive and negative ions of the nerve switch polarity and return to their original polarity, sending a neural impulse down the nerve to its endpoint (muscle).

distal
Further from the center relative to a given fixed point, as opposed to "proximal," (e.g., the facial nerve at the level of the parotid gland is distal to the portion of the nerve in the mastoid process).

electrode impedance
The electrical resistance value assigned to the capacity of the electrode to transmit current over its surface area.

electromyography
Measurement of the electrical activity generated by the contraction and relaxation of a muscle.

electroneuronography
Measurement of the capacity of a nerve to transmit an electrical signal from one point to another.

elicited response
A response to any form of stimulation, versus a spontaneous response which seems to come from no known stimuli.

event
In NIM-Response terminology, any EMG or artifact which is of an amplitude over the EVENT THRESHOLD setting on the NIM-Response. This event will cause a Tone audio response if the Tone audio is activated.

evoked response
See *elicited response.*

frequency
Number of repetitions in a given time period.

impedance
Electrical property applied to the opposition a circuit offers to the flow of current. Measured in ohms.

intensity
Strength of either a stimuli or response.

medial
More toward the middle relative to a fixed point.

monophasic waveform
A waveform which has components that lie only on one side of the original baseline. An electrical artifact is typical of this type of response pattern.

monopolar stimulation
Wide-spread cathode-to-anode relationship stimulation where the stimulator serves as one pole of the current flow and a distant (subdermal needle) electrode serves as the other pole. Recommended for "mapping" strategy in locating neural tissue.

motor nerve
Nerve which terminates in a muscle or muscle group and, when stimulated, causes muscle contraction/relaxation.

obicularis oculi muscle
Large circular muscle group surrounding the orbit of the eye.

obicularis oris muscle
Large circular muscle group surrounding the mouth.

ohm Ω
Unit of measure for resistance. One ohm is the amount of resistance in a circuit having a potential difference of one volt and a current of one ampere. 1KΩ = 1000 ohms.

Ohm's Law
A law of electrical physics describing the relationship between voltage, resistance and current delivered through an element (circuit), where the delivered current (I) is equal to voltage (E) divided by resistance (R).

oscilloscope
An instrument or part of an instrument used for viewing waveforms or other electrical information. The display usually represents frequency and amplitude characteristics of a waveform.

proximal
Closer to the center relative to a fixed point versus "distal" (e.g., the facial nerve as it exits the brainstem is proximal to where it courses through the mastoid).

pulse response
Repetitive, evenly spaced responses, usually synchronous with electrical stimulus.

resistance
A property of a conductor which causes it to impede the flow of electrons. See impedance.

sensory nerve
Nerve which terminates in a sensory end organ (e.g. hearing or vision) or serves as a sensor nerve for pain and heat.

stimulus artifact
Auditory and/or visual responses which are caused by the pulsed output of an electrical stimulator.

time display window
Horizontal scale on the NIM-Response oscilloscope, displayed in either a compressed (10 sec) or expanded (50 mS) mode.

train response
Continuous, irregular responses which usually crescendo up and down in intensity and frequency.

voltage
The force that causes electrodes to flow through a conductor.

volt
Unit of measure of the intensity of force moving through a conductor. Microvolt (μV) = 1/ 1,000,000th of a volt.

APPENDIX B • NERVE MONITORING ACCESSORIES

ORDER NO.	DESCRIPTION	NO./UNIT

NERVE INTEGRITY MONITOR

82-50110	NIM-Response HP Printer Package	1 Ea.
	Includes:	
	82-40100 NIM-Response HP Printer	1 Ea.
	82-50105 NIM-Response HP Printer Cable	1 Ea.
82-40200	NIM-Response Stand/Storage Cart	1 Ea.
82-50020	NIM-Response Storage/Carrying Case	1 Ea.
82-50200	NIM-Response Patient Interface	1 Ea.
82-20300	NIM Muting Probe	1 Ea.
82-50600	NIM-Response Patient Simulator	1 Ea.
82-50610	NIM-Response Biomed Test Package	1 Ea.
82-50004	NIM-Response Power Cord (U.S.A.)	1 Ea.
82-50003	NIM-Response User's Guide	1 Ea.
30-28800	Stainless Steel Stand with 2 shelves & 2 drawers	1 Ea.
82-50150	NIM-Response Repair Manual	1 Ea.

NIM-2 EMG ENDOTRACHEAL TUBES

Two channels of surface electrodes with 8' cables. Packaged with two green subdermal needles with 8' cables. Packaged sterile. Intended for single use only.

82-29306	6mm I.D., Protected Pin	1/Box
82-29307	7mm I.D., Protected Pin	1/Box
82-29308	8mm I.D., Protected Pin	1/Box

MONOPOLAR AND BIPOLAR STIMULATING PROBES

82-25101	Protected Pin	5/Box
	Tip and Handle packaged sterile in individual pouches intended for single use only. (Patent No. 4,892,105)	
82-25110	Standard Prass Probe Tip Dispenser Box	10/Box
82-25105	Slim Prass Probe Tip Dispenser Box	10/Box
82-25251	Yingling Monopolar Stimulating Probe Package, Protected Pin	5/Box
	Tip and Handle packaged sterile in individual pouches intended for single use only.	
82-25051	Monopolar Stimulator Handles Dispenser Box, Protected Pin	10/Box
82-25351	Kartush Concentric Bipolar Stimulator Package, Protected Pin	5/Box
	Probe and Cable packaged sterile in individual pouches. Intended for single use only.	
82-25401	Kartush Side-by-Side Bipolar Stimulator Package, Protected Pin	5/Box
	Probe and Cable packaged sterile in individual pouches. Intended for single use only.	
82-25296	Bipolar Stimulator Cable, for use with Bipolar Probe, Protected Pin	10/Box
	Stimulators are used with 82-25350, 82-25355, 82-25400 and 82-25405 Probes.	

PRASS PAIRED EMG ELECTRODES

Paired 27 g needles, 5 mm inter-electrode distance, insulated to 5 mm of tip. Twisted pair 1m cable with 2 mm pin connectors. One pair red, one pair blue with two green subdermal needles (82-27101) per package. Packaged sterile in individual pouches. Intended for single use only.

82-27301	25 mm, Protected Pin	5 Pkg/Box
82-27304	18 mm, Protected Pin	5 Pkg/Box

APPENDIX B • NERVE MONITORING ACCESSORIES (CONTINUED)

ORDER NO.	DESCRIPTION	NO./UNIT

SUBDERMAL/EEG NEEDLE ELECTRODES

LENGTH 12 mm, DIAMETER 0.4 mm, SMALL DIAMETER HUB, Protected Pin

82-27103 Stainless Steel, 1.0 meter cable 6/Box
Packaged sterile in individual pouches. Intended for single use only.

EMG HOOKWIRE ELECTRODES

82-26325 EMG Paired Hookwire Electrode ..... 2 Pr/Box
Needle length 25 mm, Wire length 1m, 2 mm pin connectors
Packaged sterile in individual pouches. Intended for single use only.

82-26326 EMG Paired Hookwire Electrode, Protected Pin ..... 2 Pr/Box

82-26625 EMG Single Hookwire Electrode 6/Box
Needle length 25 mm, wire length 1m, 2 mm pin connectors
Packaged sterile in individual pouches. Intended for single use only.

82-26626 EMG Single Hookwire Electrode, Protected Pin 6/Box

82-30000 NIM-Response Extended Service Agreement, per system (annual) ..... 1 Ea.

STIMULUS-DISSECTION INSTRUMENTS

13-52400 Kartush Stimulus-Dissection Instrument Set ..... 1 Set
Includes:

13-52401	KSD Curved Needle	1 Ea.
13-52402	KSD Elevator	1 Ea.
13-52403	KSD Ring Dissector, 3mm, Thin	1 Ea.
13-52404	KSD Ring Dissector, 2mm, Thin	1 Ea.
13-52415	KSD Cable, Protected Pin	1 Ea.
13-52407	KSD Sterilization Case	1 Ea.
13-52412	KSD Ring Dissector, 3mm, Regular	1 Ea.
13-52413	KSD Ring Dissector, 2mm, Regular	1 Ea.

13-53400 Neurotologic Stimulus-Dissection Instrument Set ..... 1 Set
Includes:

13-53401	NSD Right Angle Pick, Short	1 Ea.
13-53402	NSD Right Angle Pick, Long	1 Ea.
13-53403	NSD Curved Needle	1 Ea.
13-53404	NSD Duckbill Elevator, Medium	1 Ea.
13-53405	NSD Duckbill Elevator, Wide	1 Ea.
13-53406	NSD Round Knife, 3 mm	1 Ea.
13-53407	NSD Round Knife, 4 mm	1 Ea.
13-53408	NSD Round Knife, 5 mm	1 Ea.
13-53409	NSD Raspatory, Narrow Right	1 Ea.
13-53410	NSD Raspatory, Narrow Left	1 Ea.
13-53411	NSD Raspatory, Medium Right	1 Ea.
13-53412	NSD Raspatory, Medium Left	1 Ea.

APPENDIX B • NERVE MONITORING ACCESSORIES (CONTINUED)

ORDER NO.	DESCRIPTION	NO./UNIT
13-53413	NSD Raspatory. Wide Right	1 Ea.
13-53414	NSD Raspatory. Wide Left	1 Ea.
13-52415	Cable. Protected Pin	1 Ea.
13-52396	Sterilization Tray	1 Ea.

OTHER STIMULUS-DISSECTION INSTRUMENTS

13-52408	Sickle Knife. 5.0mm	1 Ea.
13-52409	90° Hook. 1.0mm	1 Ea.
13-52410	Crabtree - Large 3.0mm	1 Ea.
13-52411	Crabtree - Small 2.5mm	1 Ea.

APPENDIX C • APPROVED OUTPUT DEVICES

Device:	HP DeskJet™ 340 Printer
Manufacturer:	Hewlett Packard Company
Address:	8000 Foothills Boulevard Roseville, California 95747-6588
Phone:	916-786-8000
Internet:	www.hp.com
Device:	VGA / S-VIDEO converter AVerKey300 Gold™
Manufacturer:	AVerMedia
Phone:	Tel 510-770-9899
Address:	47923A Warm Springs Blvd Fremont, CA 94539
Internet:	www.avermedia.com

APPENDIX D • TECHNICAL SPECIFICATIONS

PHYSICAL DIMENSIONS

Size:	36.7 cm W x 14.7cm H x 24.9 cm D
Weight:	12.5 Kg

ENVIRONMENTAL

Operating Temperature range:	3-32° C (Operating)
Storage Temperature range:	-40 to +50° C
Humidity:	15-90% RH non-condensing
Barometric Pressure	700 - 1060 hPa

AMPLIFIER

Channels - 4:	Individually and simultaneously selectable.
Input Sensitivities:	5000 µV peak-to-peak AC-coupled.
Sensitivity Selection:	Automatically zeroed
Bandpass:	100 Hz - 2 kHz EMG Display 192 Hz – 3.2 kHz Audio EMG Speaker
Input Noise:	< 3 mV RMS @ DC - 4 kHz. inputs shorted
Input Impedance	> 250 MOhm
DC offset Rejection	± 0.770 V DC Rejection
Common Mode Rejection:	>85 dB @ 60 Hz. balanced inputs. >65 dB @ 60 Hz. 1 KΩ imbalance
Channel Enable/Disable Controls:	Dedicated function touchpads for independent channel enable/disable.
Event Threshold Control and Display:	Adjustable Graduated Touch Bar with V threshold setting displayed.
Patient Isolation	1000 V RMS 60 Hz < 500 µA Electrodes to Chassis Ground

IMPEDANCE MEASUREMENT

Control:	Dedicated ELECTRODE CHECK touchpad for measuring impedance.
Measuring Signal:	20 µA peak-to-peak, 30 Hz Square wave.
Measurement Range:	0-250 KΩ with 0.1 KΩ resolution.
Measurement Mode:	Calculated separately for each electrode including the ground electrode.

ARTIFACT DETECTION AND REJECTION

Reference Channel:	Automatic Artifact Detection by reference Channel placed in neutral tissue.
Stimulus Artifact:	Synchronized muting* adjustable by software switches.
Electrocautery Interference:	Improved automatic detection and muting* with less interference.
Electrode Lead Off:	Automatic detection, muting and warning*.

ELECTROSURGICAL REJECTION

Mute Detector TRAP Interrupt Method:	Identify/retry Failed instructions
Sensitivity to External Noise:	More electrical shielding

DISPLAY / TOUCH SCREEN

Type:	High contrast, digital, graphic electroluminescent, visible in complete darkness.
Resolution:	Display 640H x 480W pixels. Touch Panel 256H x 256W
Dedicated Function Event Touchpad Controls:	For Vertical Display, Time Display and Capture.
Vertical Display:	200, 500 and 2000 µV display modes.
Event Capture:	Enable/disable capture mode indicator on touchpad
Time Scale:	50 mS or 10 Sec display modes

APPENDIX D • TECHNICAL SPECIFICATIONS (CONTINUED)

STIMULATOR

Stimulus Type Constant:	Constant Current
Stimulus Range:	0-3 mA, maximum 12 V compliance
Stimulus Control:	Digitally controlled, adjustable in .01, .05, .2 mA steps
Stimulus Adjustment:	Dedicated, Adjustable Graduated Touch Bar with digital readout on display of command, current, and delivered current.
Stimulus Measurment	.01-3.0 mA ± .02 mA

STIMULUS CHARACTERISTICS

Waveform:	Monophasic, square pulse
Duration:	Switch selectable, 50, 100 or 250 µS
Rise Time:	Less than 0.1 mS
Rate:	Switch selectable, 1, 4, 7, or 10 Hz
Stimulus Probe:	Monopolar (standard) or bipolar (optional)

AUDIO OUTPUT

Transducers:	Built-in 4.0 inch speaker
EMG & Event Tone Signals:	Continuously processed EMG and/or activity-level dependent event tones for each channel.
Volume Preset and Limiter:	Volume Power Up Pre-set Default and a Low Volume Limiter.
"Current Delivered" Tone Signal:	Warble Tone, .05-3 mA, Measure Current > 80% Set Current.

I / O - PRINTER OUTPUT / DISK DRIVE OUTPUT

Printer Interface:	Hewlet-Parkard:	Model: DeskJet™ 340 printer, PCL5 compatible - C2655A
Connection:	Centronics Parallel 36-pin female	
I/O Isolation:	260 V RMS 60 Hz < 1 mA All I/O Connections to Chassis Ground	

VIDEO OUTPUT

Interface:	VGA Compatible, 640 x 480 resolution
Connection:	15-pin D-sub Male
Video Isolation:	264 V RMS 60 Hz < 1 mA ALL Connections to Chassis Ground

ELECTRICAL

Input Voltage	100V, 120V, 220V, and 230-240V ± 10%
Frequency	50/60 Hz ± 5%
Power Consumption:	63 W Nominal
Auxilary AC output:	250 VA Max
Line Isolation:	4000 V Peak-to-Peak 60 Hz dielectric withstand from Line Connections to Signal Ground
Patient Connections	All patient probes and electrodes are Type BF ⍓ Applied Parts.
Class	Class I Medical Device per IEC/EN 60601-1

NOTE: Medtronic Xomed reserves the right to change specifications and/or designs without notice. All Specifications are < ± 10% unless noted.

* A Proprietary Technology Feature of Medtronic Xomed

CE 0123

APPENDIX E • AGENCY APPROVALS

SAFETY

The Nerve Integrity Monitor-Response System was tested to and complies with IEC/EN 60601-1 (Medical electrical equipment Part 1-2 Collateral standard for electromagnetic compatibility). UL2601-1, CSA 22.2 No. 601, AS3200.

EMC DIRECTIVE CLASSIFICATION AND USE

The equipment complies with the EC Electromagnetic Compatibility Directive (EMCD) 89/336/EEC, as amended by 93/68/EEC, subject to the following declaration.

It is intended for use in surgical operating theaters for patient-connected intraoperative nerve monitoring during surgery.

EMISSIONS/SUSCEPTIBILITY

NIM-Response system complies with IEC/EN 60601-1-2 CISPR 22 LEVEL A.

CLASSIFICATION

The NIM-Response System is a Class I Medical Device per IEC/EN60601-1.

RADIATED ELECTROMAGNETIC FIELDS

Complies with EN60601-1-2.
The system is intended to be used with the Muting Probe which generally activates the MUTE function synchronous with exposure to excessive RFI energy. During Muting the audio and visual displays are disabled. After removal of the RFI, the muting turns off and monitoring automatically continues. Certain sources and low levels may not be detected by the muting detector and may activate the mute function.

Users of this equipment should be aware that if the Muting Probe is not used or is not activated by the RFI, then the monitor as a result of the interference may output audio and visual interference artifacts. When the unit was RFI tested without the Muting Probe, artifact was heard from the speaker and seen on the display for RFI levels from 1 V/m (80% AM 1 KHz) to 3 V/m for 26 to 1000 MHZ.

Artifact will typically produce screen and/or speaker output that has characteristics unlike repeatable evoked EMG responses. The user should confirm that the responses are not RFI induced and that EMG clearly correlates with an expected patient EMG response in the context of the surgery.

RFI artifact responses cannot convey improper information since the aberrant signal is easily recognizable by the surgical team.

APPENDIX F • REFERENCES

Beck, Douglas L., MA, and Benecke, James E. Jr., MD, FACS, *Intraoperative Facial Nerve Monitoring Technical Aspects,* Otolaryngology Head & Neck Surgery, 1990;102:270-272.

Kartush J., *Electroneurography and Intraoperative Facial Monitoring in Contemporary Neurotology,* Otolaryngology Head & Neck Surgery, 1989; 101:496-503.

Kartush J., and Bouchard, K, eds., *Neuromonitoring in Otology and Head and Neck Surgery,* New York: Raven Press, 1992.

Möller, A.R. *Evoked Potentials in Intraoperative Monitoring,* Baltimore: Williams & Wilkins, 1988.

Shallop J., *Seventh and Eighth Nerve Monitoring During Acoustic Tumor Surgery,* Seminars in Hearing, 1989; 10:346-355.

Approved
WWG 4/4/2000

Medtronic Xomed Surgical Products, Inc.
6743 Southpoint Drive North
Jacksonville, Florida 32216-0908
U.S.A.

68E3247 B 03/00

REF # 82-50003

ATTACHMENT B

Part : 8250001
Order #/Lot #: 19727500

Desc: NIM-RESPONSE MAINFRAME,115V, 1/EA
Line: 0001 Order Qty: 3.0000

[redacted]

~)s3p103h40v7,21b7,21s24670T19727500~(s0p16.67h9.5v0s0b4099T 0001

Due Date : 04/22/00
Start Date : 04/12/00

Spec Date : 02/15/00
MFG Code : 300

Non-Conformance Report #(NCR): CO-4836
00-4824
00-4860

Sterile Load: _____

DATE	****OPERATORS****	GOOD QTY	SCRAP QTY	JOB STEP	ALT OPER	FUNCT	LABOR COST CTR	WORK CENTER
5/17	TD	3		10	0001		206	06A

SU-M: L: RT-M: L: .300
ASSEMBLE
TXT:0001 1. ASSEMBLE NIM MAINFRAME PER XMI 206-054

5/17 5/18	TD TD	2 1		20	4213		206	06A

SU-M: L: RT-M: L: 10.000
FUNCTIONAL TEST
TXT:0001 1. PERFORM NIM FUNCTIONAL TEST PER XES 0337, SECTION III A.

5/17 5/18	TD TD	2 1		30	2587		206	06A

SU-M: L: RT-M: .040 L: 10.000
BURN-IN
TXT:0001 1. PERFORM NIM BURN-IN TEST PER XES 0337, SECTION III B.

5/25 5/26	QC QC	2 1		40	0158		206	06A

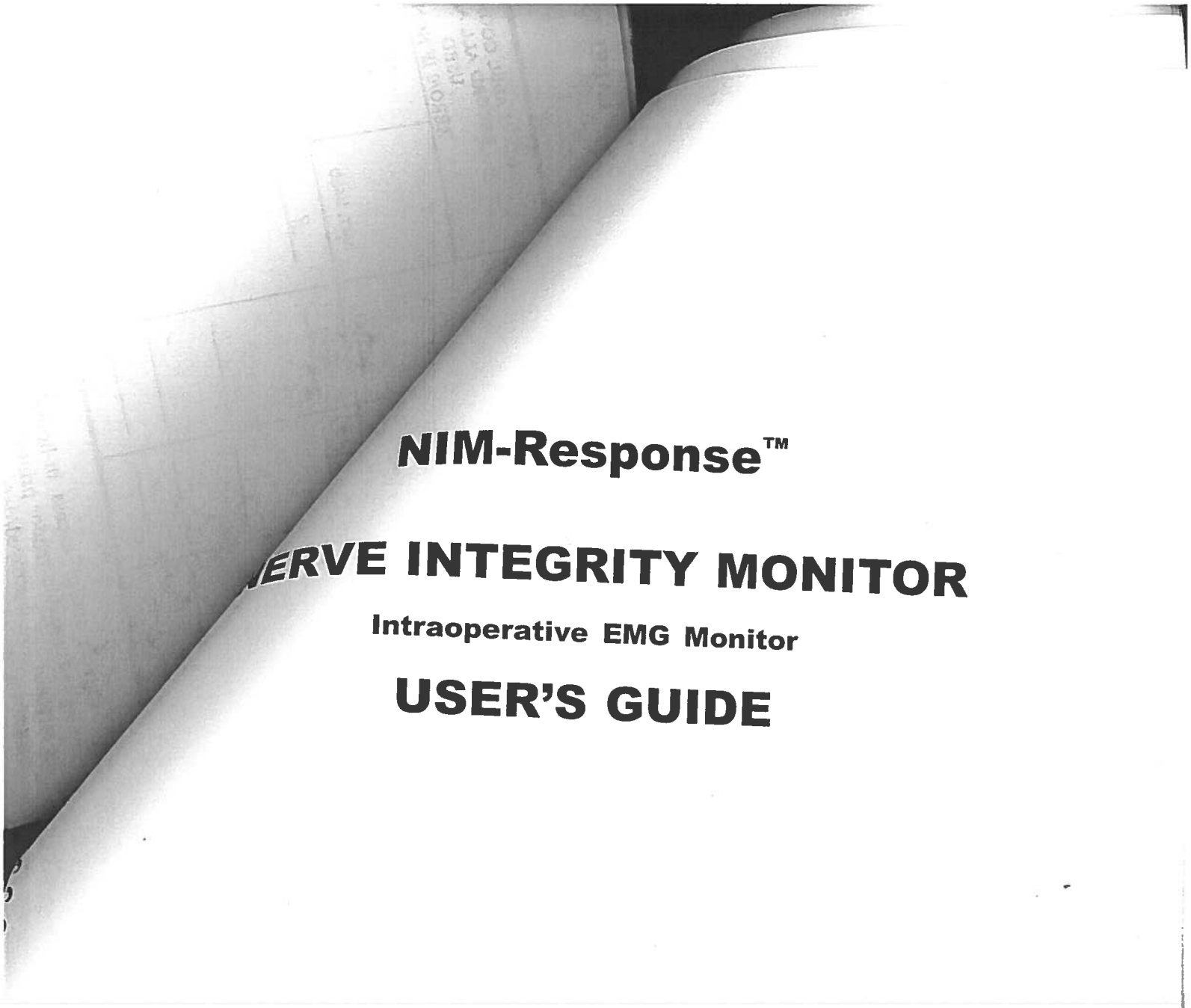
SU-M: L: RT-M: L: .500
TEST MAINFRAME ASSEMBLY
TXT:0001 1. SYSTEM SECURITY: REMOVE COVER AND VERIFY ALL
TXT:0002 CABLES, BOARDS, AND COMPONENTS ARE SECURE.
TXT:0003 100 % INSPECT VISUAL ACC 2/1 REJ 0/0
TXT:0004
TXT:0005 2. PERFORM NIM FINAL TEST PER XES 0337, SECTION III AND IV FOR ONE
TXT:0006 UNIT. TEST REMAINING UNITS PER XES 0337, SECTION III ONLY.
TXT:0007
TXT:0008 100% INSPECT VISUAL ACC 2/1 REJ 0/0

5/26	JQ	2 +60		50	7573		206	06A

SU-M: L: RT-M: L: 2.000
Q.A. INSPECT
TXT:0001 1. INSPECT PER THE FOLLOWING:
TXT:0002 SYSTEM VISUAL: VERIFY BURN-IN PERIOD COMPLETED AND VISUALLY
TXT:0003 INSPECT POWER SWITCH, FRAME, DECALS, JACKS & LCD FOR
TXT:0004 APPEARANCE & ALIGNMENT. PLACE CUSTOM/NORMAL SWITCH IN THE

D.H.R. DEPT. REVIEWED MAY [illegible] 2000 COORDINATOR #4

2 - Partial 5/26/00 TD



NIM-Response™

ERVE INTEGRITY MONITOR

Intraoperative EMG Monitor

USER'S GUIDE

Medtronic
XOMED

NIM-Response Helpline
1-800-874-5797
For Questions and Service

Medtronic Xomed Surgical Products, Inc.
6743 Southpoint Drive North
Jacksonville, Florida 32216-0908
U.S.A.

68E3247 B 03/00

5/19/00

REF # 82-50003

ATTACHMENT C

SALES_ORDER	LINE	ITEM	LOT	SERIAL	AR_DOC	SO_SHIP_DATE	CUSTOMER	CUS_PO	NAME	ADDR1	ADDR2	ADDR3	CITY	STATE	ZIP	COUNTRY
1319647	0002	8250001	19727500	000056	1337023	05/26/2000 00:00:00	0557018	9134007	BOCA RATON COMM HOSPITAL	800 MEADOWS RD			BOCA RATON	FL	33486	USA
1317631	0002	8250001	19727500	000055	1337243	05/26/2000 00:00:00	2957271	ERIC	GOSSE ERICK	DO NOT MAIL			XXX	XX		USA
1322022	0002	8250001	19727500	000055	1337313	05/26/2000 00:00:00	4101080	DAVE EWER	KAISER FOUNDATION HOSPITAL	A/P DEPT-CAPITAL PROCESSING	PO BOX 12929		OAKLAND	CA	946042929	USA
1314475	0002	8250001	19727500	000054	1337374	05/26/2000 00:00:00	4801230	521898001	MANATEE MEMORIAL HOSP.	206 2ND ST E			BRADENTON	FL	342080000	USA

ATTACHMENT D

MEDTRONIC, INC.
WORK ORDER HISTORY FOR 8250001 (NIM-RESPONSE MAINFRAME,115V, 1/EA)

Seq	Work Order	Line Type	Order Qty	Open Date	Start Date
001	**19435700**	0001 STK	10.0000	02/02/00	03/19/00
	Due Date: 03/28/00		Details<		
002	19481400	0001 STK	10.0000	02/09/00	03/24/00
	Due Date: 04/02/00		Details<		
003	19504600	0001 STK	10.0000	02/15/00	03/24/00
	Due Date: 04/02/00		Details<		
004	19582900	0001 STK	10.0000	03/03/00	05/01/00
	Due Date: 05/10/00		Details<		
005	19605400	0001 STK	10.0000	03/08/00	05/17/00
	Due Date: 05/26/00		Details<		
006	19727300	0001 STK	3.0000	03/31/00	05/17/00
	Due Date: 05/26/00		Details<		
007	19727400	0001 STK	3.0000	03/31/00	06/19/00
	Due Date: 06/28/00		Details<		
008	19727500	0001 STK	3.0000	03/31/00	05/17/00
	Due Date: 05/26/00		Details<		
009	19754100	0001 STK	3.0000	04/04/00	11/17/00
	Due Date: 11/28/00		Details<		
010	19943300	0001 STK	1.0000	05/11/00	09/24/00
	Due Date: 09/28/00		Details<		
011	19943400	0001 STK	1.0000	05/11/00	09/24/00
	Due Date: 09/28/00		Details<		
012	20020200	0001 STK	3.0000	05/25/00	06/23/00
	Due Date: 07/02/00		Details<		
013	20020300	0001 STK	3.0000	05/25/00	06/19/00
	Due Date: 06/28/00		Details<		
014	20043400	0001 STK	2.0000	05/31/00	06/23/00
	Due Date: 07/02/00		Details<		
015	20043500	0001 STK	2.0000	05/31/00	06/23/00
	Due Date: 07/02/00		Details<		
016	20043600	0001 STK	13.0000	05/31/00	09/14/00
	Due Date: 09/18/00		Details<		
017	20043700	0001 STK	2.0000	05/31/00	06/09/00
	Due Date: 06/18/00		Details<		
018	20043800	0001 STK	2.0000	05/31/00	06/09/00
	Due Date: 06/18/00		Details<		
019	20162600	0001 STK	9.0000	06/26/00	11/17/00
	Due Date: 11/28/00		Details<		
020	20268400	0001 STK	10.0000	07/14/00	10/01/00
	Due Date: 10/05/00		Details<		
021	20302700	0001 STK	10.0000	07/20/00	08/09/00
	Due Date: 08/18/00		Details<		
022	20360200	0001 STK	10.0000	07/31/00	09/14/00
	Due Date: 09/18/00		Details<		
023	20360500	0001 STK	10.0000	07/31/00	09/14/00
	Due Date: 09/18/00		Details<		

Seq	Work Order	Line Type	Order Qty	Open Date	Start Date
024	20490600 0001	STK	5.0000	08/21/00	09/27/00
Due Date: 10/01/00			Details<		
025	20490700 0001	STK	5.0000	08/21/00	10/19/00
Due Date: 10/23/00			Details<		
026	20655100 0001	STK	5.0000	09/14/00	10/19/00
Due Date: 10/23/00			Details<		
027	20655200 0001	STK	5.0000	09/14/00	10/19/00
Due Date: 10/23/00			Details<		
028	20732600 0001	STK	5.0000	09/29/00	10/19/00
Due Date: 10/23/00			Details<		
029	20732700 0001	STK	5.0000	09/29/00	11/01/00
Due Date: 11/05/00			Details<		
030	21008300 0001	STK	5.0000	11/17/00	11/17/00
Due Date: 12/30/00			Details<		
031	21096600 0001	STK	5.0000	12/04/00	12/04/00
Due Date: 12/30/00			Details<		
032	21115900 0001	STK	1.0000	12/05/00	12/29/00
Due Date: 01/08/01			Details<		
033	21133300 0001	STK	15.0000	12/07/00	12/07/00
Due Date: 01/15/01			Details<		
034	21180300 0001	STK	1.0000	12/12/00	01/06/01
Due Date: 01/15/01			Details<		
035	21245800 0001	STK	3.0000	12/22/00	12/22/00
Due Date: 01/05/01			Details<		
036	21249500 0001	STK	4.0000	12/27/00	01/11/01
Due Date: 01/20/01			Details<		
037	21254600 0001	STK	3.0000	12/27/00	12/27/00
Due Date: 01/10/01			Details<		

Data collected from the Medtronic Xomed CHESS ERP System on March 18, 2010
\\jaxm1bnas02\home01\heshcs1\DOCS\WORD Docs\WO HISTORY 8250001.doc